***FOR PUBLICATION**

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RONALD SOLOMON,	:	
		Civil Action No. 07-1102 (FLW)
Plaintiff,	:	
v.		
	:	**OPINION**
BRISTOL-MYERS SQUIBB CO., et al.,	:	
Defendants.	:	

WOLFSON, District Judge:

Plaintiff Ronald Solomon ("Plaintiff" or "Mr. Solomon") 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 he 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 Texas state and common law claims against Defendants, including Failure-to-Warn, Defective Design, Manufacturing Defect and Negligence.[1] Before the Court is

[1] In his 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 his Complaint to assert causes of action arising only under Texas state law. See Opinion dated December 30, 2009, pp. 2-3. Therefore, Texas law controls on

Defendants' motion for summary judgment based upon a number of theories, including the learned intermediary doctrine under Texas 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 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

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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 Mr. Solomon 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., Texas, to the facts presented in this particular case.

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

syndrome ("ACS").[4] Id. at ¶ 4.

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 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

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[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).

[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. Plaintiff contests the accuracy of these clinical trials; those arguments will be further discussed in this Opinion.

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.

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 Medical History

Plaintiff has a history of coronary artery disease and vascular related health issues. His first angioplasty to clear coronary arteries occurred in 1997. See Columbia Medical Center of San Angelo Medical Record dated July 21, 1997. Plaintiff has

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

undergone at least seven surgeries to ameliorate his cardiovascular-related issues. In November 2002, Plaintiff suffered a heart attack and he was diagnosed with acute myocardial infraction. See Shannon West Texas Memorial Hospital Discharge Summary. To remediate his condition, Plaintiff's doctors, inter alia, placed two metal stents in his arteries to maintain blood flow to his heart. Id. At that time, the interventionalist cardiologist, Dr. Randy McCullough, prescribed Plaintiff Plavix with aspirin in order "to prevent clots." See Dr. McCullough Dep., T56:5-19. Subsequently, Plaintiff's treating cardiologist, Dr. Gene Sherrod, and his clinical nurse specialist, Kim Coon, continued this prescription until July 2005. See Dr. Sherrod Dep, T125:19 - 126:7.

In July 2005, Plaintiff began suffering gastrointestinal bleeding. See Dr. Hunt's Examination Report dated August 5, 2005. He was admitted to the hospital for an acute gastrointestinal bleed, and was instructed to stop taking Plavix, but to continue aspirin. See Id. After the discontinuation of Plavix, Plaintiff, for over two months, continued to experience gastrointestinal bleeding and was treated with blood transfusions. See Operative Report dated September 30, 2005. On September 30, 2005, to stop the chronic bleeding, Plaintiff had surgery for bowl resection, gallbladder removal, and hernia repair. Id.

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, under Texas state law, for defective design, manufacturing defect, failure to warn, and negligence.[7] See Am. Compl., Count I - Count IV. 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, 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. It is this issue upon which the Court will focus.

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

[7] On December 30, 2009, this Court dismissed Plaintiff's claims for negligent misrepresentation (Count V) and for violation of the Texas Deceptive Trade Practices Act (Count VI). See Order dated December 30, 2009.

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. 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 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. Texas Failure-to-Warn Claim

Plaintiff's theory is relatively straightforward: Defendants failed to adequately warn Plaintiff and his prescribing physicians

of the potential for bleeding complications from taking Plavix. More specifically, Plaintiff insists that his prescribing physicians were not warned 1) regarding the substantial risk of serious bleeding caused by taking Plavix with aspirin; 2) that Plaintiff should have been genetically tested to determine his genetic response to Plavix; 3) that Plavix is entirely inefficacious in an individual who takes the drug more than one year after being implanted with a stent; 4) that taking Plavix is not more effective than taking aspirin alone; and 5) that Plavix is entirely ineffective in non-smokers.

Generally, under Texas law, a manufacturer is required to provide an adequate warning to the end users, e.g., consumers of its product if it knows or should know of any potential harm that may result from the use of its product. Centocor, Inc. v. Hamilton, 372 S.W. 3d 140, 153-54 (Tex. 2012)(citing Bristol Myers Co. v. Gonzales, 561 S.W. 2d 801, 804 (Tex. 1978)); Pavlides v. Galveston Yacht Basin, Inc., 727 F.2d 330, 338 (5th Cir. 1984) (finding that under Texas law, "a manufacturer must instruct consumers as to the safe use of its product and warn consumers of dangers of which it has actual or constructive knowledge at the time the product is sold."). In certain situations, however, "the manufacturer's or supplier's duty to warn end users of the dangerous propensities of its product is limited to providing an adequate warning to an intermediary, who then assumes the duty to

pass the necessary warnings on to the end users." Centocor, 372 S.W. 3d at 154. Specifically within the prescription drug context, "where a plaintiff sues the manufacturer of a prescription drug for failing to adequately warn of the drug's effects, Texas courts employ the learned-intermediary doctrine." Pustejovsky v. PLIVA, Inc., 623 F.3d 271, 276 (5th Cir. 2010)(citing Alm v. Aluminum Co. of Am., 717 S.W.2d 588, 591 (Tex. 1986)).[8]

As the Texas Supreme Court has explained, "the underlying premise for the learned intermediary doctrine is that prescription drugs are complex and vary in effect, depending on the unique circumstances of an individual user, and for this reason, patients can obtain them only through a prescribing physician." Centocor, 372 S.W.3d at 154. The Court went on to state that "the bedrock of [the] healthcare system is the physician-patient relationship, and the ultimate decision for any treatment rests with the prescribing

[8] Plaintiff implores this Court to reject the learned intermediary doctrine when examining Texas product liability laws. In so doing, Plaintiff relies on a decision rendered by the West Virginia Supreme Court in State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E. 2d 899 (W. Va. 2007), wherein the Court eliminated the learned intermediary doctrine in that state. As Plaintiff should be aware, because Texas law controls in this case, this Court, sitting in diversity, is bound to follow state law as announced by the highest court in Texas. See Nuveen Mun. Trust v. Withumsmith Brown, P.C., 692 F.3d 283, 315 (3d Cir. 2012). And, the Texas Supreme Court has recently reaffirmed the viability and application of the learned intermediary doctrine in Centocor in the context of prescription drugs. See Centocor, 372 S.W. 3d at 154. In so holding, the Texas Court considered, and rejected, the reasoning espoused by the West Virginia Supreme Court.

physician and the patient. As a matter of both necessity and practicality, the duty to warn the patient of the potential risks and possible alternatives to any prescribed course of action rests with the prescribing physician." Id. at 166. For these reasons, the Court held that "in most prescription drug contexts, the learned intermediary doctrine applies and the duty to warn the patient rests solely with the prescribing physician." Id. at 167. Indeed, a patient's doctor, who stands between the patient and the manufacturer, is in the best position to professionally evaluate the patient's needs, assess the risks and benefits of available drugs, prescribe one, and supervise its use. See Ackermann v. Wyeth Pharms., 526 F.3d 203, 207 (5th Cir. 2008). Hence, "[i]f the doctor is properly warned of the possibility of a side effect and is advised of the symptoms normally accompanying the side effect, it is anticipated that injury to the patient will be avoided." Id. Recognizing the doctor-patient relationship, the doctrine excuses a drug manufacturer "'from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers.'" Id. (quoting Porterfield v. Ethicon, Inc., 183 F.3d 464, 467-68 (5th Cir. 1999)).

In Texas, to recover for failure to warn under the learned intermediary doctrine, a plaintiff must show that (1) the warning was defective, and (2) the failure to warn was a producing cause of the injury. Ackerman, 526 F.3d at 208. Worded differently, "a

plaintiff who complains that a prescription drug warning is inadequate must also show that the alleged inadequacy caused the doctor to prescribe the drug." McNeil v. Wyeth, 462 F.3d 364, 372 (5th Cir. 2006) (internal quotations omitted). This is because under the learned intermediary doctrine, if the doctor was "'aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the injury' and the plaintiff's recovery must be denied." Ackerman, 526 F.3d at 208 (quoting Porterfield, 183 F.3d at 468). "Even if the physician is not aware of a risk, the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would have not used or prescribed the product.'" Id. (citations and quotations omitted)(emphasis added); see Dyer v. Danek Med., Inc., 115 F. Supp. 2d 732, 741 (N.D. Tex. 2000); Willett v. Baxter Int'l, Inc., 929 F.2d 1094, 1099 (5th Cir. 1991); see also Burton v. Am. Home Prods. Corp., 955 F. Supp. 700, 710-11 (E.D. Tex. 1997). To be clear, the learned intermediary is not an affirmative defense and therefore, the burden of proof always lies with the plaintiff to establish that the complained-of warning was defective and that the failure to properly warn was a producing cause of the injury. Ebel v. Eli Lilly & Co., 321 Fed. Appx. 350, 355 (5th Cir. 2009); Centocor, 372 S.W. 3d at 164.

Before I discuss the application of the learned intermediary doctrine, I first address Plaintiff's argument regarding the "Read and Heed" presumption. Plaintiff contends that he is entitled to a heeding presumption that proper warnings would have a made a difference and that this presumption excuses him from proving causation. However, Texas law creates no such presumption. The Fifth Circuit, in Ackerman, made clear that "neither Texas nor federal courts applying Texas law have applied the read-and-heed presumption to pharmaceutical cases involving learned intermediaries." Ackerman, 526 F.3d at 212. Indeed, the court explained that "Texas has explicitly rejected the Restatement (SECOND) Of Torts § 402A, Comment j's 'read-and-heed' presumption for policy reasons and because it has been superseded by Restatement (THIRD) Of Torts::Products Liability § 2." Id. at 213 (citing Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328, 336-37 (Tex. 1998)); Koenig v. Purdue Pharma Co., 435 F. Supp. 2d 551, 556-57 (N.D. Tex. 2006)(stating expressly that the read-and-heed presumption does not apply in cases involving learned intermediaries). Furthermore, the Fifth Circuit predicted that the Texas Supreme Court is unlikely to apply the "Read and Heed" presumption involving learned intermediaries. Ackerman, 526 F.3d at 213. And, Plaintiff has not provided the Court with any recent authority that would suggest otherwise. Accordingly, contrary to

Plaintiff's position, the Court will not apply such presumption in this case. I now turn to the learned intermediary doctrine.

A. Accuracy of Plavix's Warning Label

Plaintiff's failure-to-warn claim fails because the learned intermediary doctrine excuses Defendants from liability in this case. As noted above, Plaintiff complains that Defendants did not adequately warn about the substantial risk of serious bleeding caused by taking Plavix with aspirin, that Plavix is ineffective for a non-smoker, and that Plavix loses its efficacy for patients who take the drug for more than one year after being implanted with stents. Indeed, Plaintiff dedicates much of his arguments to the effectiveness of Plavix.

As an initial matter, this Court finds that although Plaintiff presents various studies and articles challenging the efficacy of Plavix in certain types of patients, none of those studies are relevant to Plaintiff's medical situation. For example, according to Plaintiff's expert, Dr. Moye, the Defendant-sponsored MATCH study in 2004 found that Plavix and aspirin was no better than aspirin alone in treating patients with recurrent transient ischemic stroke events. In that regard, based on an article published by the American Heart Journal, Plaintiff claims that more than 40% of Plavix use was for conditions where there was no evidence that Plavix had any effectiveness over aspirin or any effectiveness at all. See Pl.'s Ex. 16. Plaintiff credits

Defendants' aggressive marketing as the reason why physicians continue to prescribe Plavix in the absence of evidence of efficacy. See Pl. Ex. 28. Notwithstanding this position, Plaintiff, however, did not suffer from transient ischemic stroke. Thus, this study is irrelevant to Plaintiff's claim.

In fact, the majority of the efficacy studies of Plavix cited by Plaintiff are unrelated to Plaintiff's personal circumstances. In one example, Plaintiff cites certain studies to show that Plavix is ineffective as post-operative treatment for coronary bypass. See Pl. Ex. 20. However, Plaintiff was not treated with Plavix after his bypass operation, rather he was treated with stents. Similarly, the studies upon which Plaintiff rely regarding Plavix's ineffectiveness for patients 75 years or older has no relevance since Plaintiff was well under 75 years old when he stopped taking the drug. See Watson Cert., Ex. E. Another glaring example is Plaintiff's reliance on studies that have found that Plavix, when taken alone, is not more effective than taking aspirin by itself. See Pl. Exs. 5, 7. As Plaintiff concedes, however, he took Plavix in combination with aspirin, and therefore, any evidence comparing the efficacy of aspirin taken alone and Plavix taken alone has no bearing on Plaintiff's case. Overall, Plaintiff has failed to explain how any of the studies regarding efficacy are relevant to the adequacy of the warnings with respect to Plaintiff's health condition, i.e., ACS. Thus, the studies based on the efficacy of

Plavix, as presented by Plaintiff on this motion, fail to raise a genuine issue of material fact on the question of whether Plavix's warnings were adequate.[9]

Moreover, it appears that Plaintiff's efficacy arguments are not relevant in the context of a failure-to-warn analysis. Plaintiff's claim is essentially premised on the fact that he suffered substantial bleeding as a result of taking both Plavix and aspirin at the same time - not that Plavix did not work. As the Court has previously noted, in Texas, a drug manufacturer is required to provide an adequate warning of its product if it knows of any potential harm that may result from the use of its product. In other words, a proper warning should adequately alert any danger or harm that may result from ingesting the drug. See Reese v. Mercury Marine Div. of Brunswick Corp., 793 F.2d 1416, 1420 n.1 (5th Cir. 1986). Permitting Plaintiff to pursue his failure-to-warn claim on an efficacy theory would, as has been found in other jurisdictions with similar laws, impermissibly expand liability under Texas law on the adequacy of pharmaceutical warning labels. See, e.g., In re Fosamax Prods. Liab. Litig., No. 06-1789, 2010 U.S. Dist. LEXIS 33260, at * 14-15 (S.D.N.Y. Mar. 26, 2010)("To allow Plaintiff to pursue a claim for the 'failure to warn' of the efficacy of a drug would be an expansion of liability under Florida

[9] Furthermore, as discussed infra, if the studies are not relevant to Plaintiff's condition, then the failure to inform the physicians of such findings cannot establish causation.

law."); Tobin v. Astra Pharmaceutical Prods., Inc., 993 F.2d 528, 536 (6th Cir. 1993), abrogated on other grounds by J. McIntyre Machinery, Ltd. v. Nicastro, 131 S.Ct. 2780 (2011)(finding that the plaintiff's argument regarding the efficacy of the drug, ritodrine, should not be made in the context of a failure-to-warn claim.); Neeham v. White Labs., Inc., 639 F.2d 394, 402 (7th Cir. 1981).

The remaining studies and expert opinions upon which Plaintiff rely are simply not sufficient to show that the warnings regarding the risks of bleeding in patients who suffer from ACS, were inadequate at the time Plaintiff was on dual therapy. As explicated earlier, in prescription drug cases involving the learned intermediary doctrine, Texas law is clear: when "a warning specifically mentions the circumstances complained of, the warning is adequate as a matter of law." Rolen v. Burroughs Wellcome Co., 856 S.W. 2d 607, 609 (Tex. App. 1993). In that connection, in cases where the dispute lies with the particular risk level that a warning label publishes, the plaintiff must present sufficient evidence to demonstrate that the published risk level is inaccurate or misleading. Id.; Murthy v. Abbott laboratories, 847 F.Supp. 2d 958, 968 (S.D. Tex. 2012). For instance, "[w]arning the learned intermediary of a much lower risk than the actual risk could render the warning not just misleading, but ineffective." Id. "Thus, if the manufacturer decides to label a risk as 'comparatively rare'

and also to provide a numerical quantification of that risk, that number must be within a certain degree of accuracy." Id.

In this case, first and foremost, the warning label clearly cautions users that "PLAVIX use with aspirin was associated with an increase in bleeding compared to placebo with aspirin. There was an excess in major bleeding in patients receiving PLAVIX plus aspirin compared with placebo plus aspirin, primarily gastrointestinal . . . sites." See February 2002 Plavix Labeling. In addition, the label references a table, taken from the CURE study, which publishes statistics regarding incidence of bleeding when taking Plavix and aspirin together compared to taking aspirin with a placebo (e.g., Major bleeding: 3.7% v. 2.7%). See Id., Table 3. Plaintiff does not dispute that this label, which was in effect when he was prescribed the drug, warned of the particular incidence of bleeding experienced by patients – like Plaintiff – who took Plavix with aspirin. Rather, it appears Plaintiff contends that those warnings were inaccurate.

However, Plaintiff's evidence is insufficient to establish a genuine issue of material fact on the accuracy of the warning label: aside from the evidence regarding the efficacy of Plavix – which this Court has discounted – Plaintiff fails to provide any evidence to show that the risk levels published on the Plavix warning label were inaccurate, insofar as the warnings concern the risk of bleeding in ACS patients who take both Plavix and aspirin.

Indeed, some of the medical evidence upon which Plaintiff relies indicate that when taking Plavix and aspirin in combination, there is an increased risk of bleeding, which risks are already displayed on Plavix's warning label. For example, Plaintiff references the CHARISMA trial study which primarily compared the effectiveness of long-term treatment by patients taking Plavix plus aspirin with patients taking aspirin alone. The study concluded that "[i]n summary, the combination of clopidogrel plus aspirin was not significantly more effective than aspirin alone in reducing the rate of myocardial infraction . . . ." See Pl. Ex. 14, p. 1714. While the study went on to note that "the risk of moderate-to-severe bleeding was increased," see Id., there is no indication that the results of the study contradict those risk levels found on the Plavix warning label. In that regard, Plaintiff fails to explain how the results of the CHARISMA study undermine Plavix's published warnings. Perhaps even more crucial is the fact that the findings of the CHARISMA study were published in 2006 – a year **after** Plaintiff stopped taking Plavix. Therefore, those findings cannot bolster Plaintiff's failure-to-warn claim since this study was not available at the time Plaintiff was taking Plavix.

In addition, Plaintiff points to an email written in 1999 by Melvin Blumenthal, Executive Director for Global Clincial Development at BMS, wherein he expressed concerns regarding higher rates of bleeding when treating **stroke** patients with Plavix and

aspirin at the same time. See Blumenthal Email dated February 4, 2007. In that connection, Plaintiff referenced an April 2004 email sent by Blumenthal which indicated that the outcome of the MATCH[10] study revealed that the then-Plavix warning label was relatively "weak" regarding the risks of bleeding in patients who suffered **ischemic stroke or transient ischemic attack**. See Blumenthal Email Dated April 13, 2004. Since Plaintiff did not suffer a stroke at the time he was taking Plavix, this study has no relevance in showing that the Plavix warning label was inaccurate regarding the risks of bleeding in patients – like Plaintiff – who suffer from ACS. Furthermore, Plaintiff does not cite to any evidence or authority that links the results of the MATCH study to patients with ACS. Similarly unconvincing is the June 2005 Opinion piece published in the CHEST Journal, which highlights certain findings regarding the use of Plavix after a coronary artery bypass grafting. See Pl. Ex. 21. As noted earlier, Plaintiff took Plavix after the placement of stents - not bypass surgery. More importantly, Plaintiff does not explain how this article and the authors' opinion impact the accuracy of Plavix's warning label, other than to suggest that there is a risk of increased bleeding

[10] The MATCH study was conducted to compare the side effects of patients who took aspirin and Plavix after recent ischemic stroke or transient ischemic attack, with those stroke patients who took only Plavix. See Pl. Ex. 13. Because the study was not conducted with patients who suffer from ACS, I need not detail the specifics of the MATCH study as it is immaterial to the issues in this case.

when taking Plavix and aspirin - which risk was already warned by Defendants.

Finally, the Court will discuss the opinions of Plaintiff's expert, Dr. Moye. In Dr. Moye's expert report, he opines on the efficacy of Plavix taken by patients with ACS. See Dr. Moye's Report p. 1. Essentially, it is his opinion that due to the risks of increased bleeding and low efficacy of Plavix in certain populations of patients, there is no special benefit of prescribing Plavix to those patients. Id. The expert goes on to explain certain studies preformed on Plavix, some of which were sponsored by Defendants, e.g., CAPRIE, CURE and CREDO. His ultimate conclusions were derived from the analyses of those studies. Of particular relevance, Plaintiff argues that Dr. Moye has opined that Plavix is not effective when taken long term; that "identifying the optimal duration of the Plavix/[aspirin] effect is an important public health issue in the management of ischemic heart disease." Id. at p. 43-44. However, lacking in Dr. Moye's report is any conclusion as to how his opinions affect Plaintiff's Plavix prescription, or how Plavix's warning label should have reflected the duration of therapy and the impact of a long term therapy on the risk of increased bleeding. Moreover, Plaintiff suggests that Defendants should have warned that Plavix is not

effective for non-smokers.[11] As Plaintiff is aware, his own evidence does not conclusively show that Plavix is ineffective on non-smokers. See Pl. Ex. 40, p. 2496 (clinical study noted that the "influence of smoking status on clopidogrel metabolism is currently being evaluated in a prospective study.") And, Dr. Moye's report only states that the effect of Plavix "in nonsmokers depends on the circumstances. In those indications where Plavix has a demonstrable effect, the effect in nonsmokers is also non-negative. However, in patients in whom Plavix is relatively non-effective, representing most of the patient population, Plavix remains ineffective in smokers." Dr. Moye's Report, p. 46. Clearly, this broad statement does not stand for the proposition that Plavix is not effective for non-smoking patients. Thus, the Court cannot find that Plaintiff has presented sufficient evidence to show that there is a genuine issue of material fact that Plavix's warning label was inaccurate.

In sum, on the issue of the accuracy of Plavix's warning label, Plaintiff presents a number of studies and articles which are neither relevant nor probative in demonstrating that the warnings regarding the risks of increased bleeding in ACS patients taking Plavix and aspirin were inaccurate in any way. Despite

[11] Plaintiff conceded that he smoked as much as three or four packs a day until 1978, see Solomon Dep., T48:4-12, and that at the time Plaintiff was taking Plavix, he was also using oral tobacco products. See McCullough Dep. at T31:23-32:2.

Plaintiff's assertion to the contrary, "determining that a party has failed to established an essential element of the claim is a proper consideration on summary judgment and is not a finding of fact to be left to the jury." Ebel, 321 Fed. Appx. At 357. Therefore, without adducing evidence to show that the specific risk levels referenced in Plavix's warning label are somehow inaccurate, Plaintiff fails on this motion to establish the first prong of his failure-to-warn claim.

B. Causation

In addition to proving inaccuracy, Plaintiff has to show that the allegedly defective warning label is the producing cause of Plaintiff's injury. See Ackerman, 526 F.3d at 208. Simply put, it is Plaintiff's burden to demonstrate that the treating physician would not have used or prescribed the product but for the inadequate warning. Having reviewed Plaintiff's treating physicians' testimony, the Court finds that Plaintiff has also failed to carry his burden on this prong.

As the interventionalist, Dr. McCullough testified that Plaintiff was placed on Plavix and aspirin in 2002 because Plaintiff "has demonstrated he has multivessel disease. In other words, it not only involved his heart, he had to have bypass surgery; but he's also had what sounds like an arterial embolus, a piece of material either a clot or a piece of plaque or blockage that's broken loose and gone to . . . the arteries feeding his

colon; he had to have his colon removed. And he's had – both arteries in his neck had to be operated on because of arteriosclerotic disease." Dr. McCullough's Dep., T28:16-24. In addition, Dr. McCullough explained that based upon Plaintiff's medical situation, there was a strong likelihood of blood clotting with the placement of stents in Plaintiff's arteries. Id., T49:13-50:2. The doctor determined that placing Plaintiff on dual therapy with Plavix and aspirin indefinitely was the best treatment at the time. Indeed, Dr. McCullough was aware that there were risks associated with this type of treatment. He explained: "The thing that we're giving the medication for is to – for the prevention of blood clots. So any time you give a medication that can prevent blood clots, its going to increase the risk of bleeding as well; or . . . some blood loss." Id., T63:2-9. Importantly, Dr. McCullough acknowledged that dual therapy could cause serious risk of bleeding in patients. Id., T63:1-10. However, the cardiologist insisted that despite the risks, it was important that these drugs were prescribed to Plaintiff to prevent "a condition called subacute thrombosis. And it is a life-threatening problem that will actually cause the blockage – that artery to block off by a clot if it happens. And I've seen it happen on cessation of aspirin and/or Plavix; even sometimes beyond the recommended dose interval." Id., T64:13-20. In fact, Dr. McCullough goes so far as to explain that the standard of medical practice today, let alone in 2002, is to

provide the combination of Plavix and aspirin for patients like Plaintiff. Id., T65:18-23.

Furthermore, throughout Dr. McCullough's deposition, he consistently testified that he did not rely on Plavix warning labels when putting Plaintiff on dual therapy with Plavix and aspirin. See Id. T58: 8-17. Dr. McCullough explained:

> Well, of course, you know these drugs are studied by research-minded interventional cardiologists all over the world, and so our publications and things that we read . . . our so called trade journals, plus articles that come out. [T]hat's how they come up with the new recommendations of how you treat . . . . I would say most of really . . . pay attention to what our colleagues in the research realm are doing, and those are where our recommendations come from.

Id., T58:8-59:4. Essentially, Dr. McCullough represented that he typically relies on guidelines from the medical community and his colleagues' opinions rather than the labels for the drug he prescribes to patients. Id., T61:3-11; T86:13-21 ("I'm not really depending on the drug company . . . . As I said, this is more information we get from so-called trade journals, like JACC, the interventional journals as well as . . . updated things for our societies."); T91:4-20 ("And again, the people that I get my recommendations from really are not from the drug companies themselves. I mean, I don't . . . talk to physicians at the drug companies . . . . I try to learn what I need to learn from my colleagues and the people that are doing the same thing that I'm doing that actually do the research.").

Ultimately, Dr. McCullough reiterated that he would not have prescribed anything different to Plaintiff knowing what he knows about Plavix today:

> Q: Based on what you've seen today in Mr. Solomon's records, and the information regarding his history, what you found during the cath and what you did during the cath, do you believe that your prescription of Plavix and aspirin to him was appropriate?
>
> A: Yes, I do.
>
> Q: If he presented today to you with all the signs and symptoms and history that we saw in his records today, do you think you would place him on Plavix and aspirin today?
>
> A: There are several options now, but yes.
>
> * * *
>
> Q: Do you believe your patients have benefitted from taking Plavix and aspirin following stent placement?
>
> A: I believe that to be true . . . It may have prevented them from having a life threatening event, I would say.

Id., T110:3-112:20.

Likewise, Plaintiff's treating physician, Dr. Sherrod, echoes Dr. McCullough's opinions. Indeed, Dr. Sherrod was well aware of the risks of bleeding when prescribing Plavix and aspirin to his patients. See Dr. Sherrod's Dep., T39:3-22. In fact, the doctor

stated that the medical community knew about the significant bleeding risk "ever since [Plavix] came out." Id., T40:1-3. However, Dr. Sherrod acknowledged that while he "understand[s] that there's risk to giving [Plavix and aspirin] when we give it, and the patient understands that there's a risk . . . [of] bleeding. . . but if you stop it, you have a high risk, or a significant risk of having something bad happen to you. Because I think the benefits are – outweigh the risks. Like I said, though, periodically you have a disaster, and it can be bad." Id., T42:6-13; see Id., T47:23-4812; T72:14-73:7. Dr. Sherrod, like Dr. McCullough, received, and continues to receive, information regarding potential risks and benefits of a particular drug from "things on the internet . . . available through clinic and through the hospital that pulls information, prescribing information, doses, indications, complications, adverse reactions, interactions with other medications." Id., T50:2-9. Significantly, Dr. Sherrod also represented that based on the information regarding Plavix at this time, it would not have changed his medical decision to place Plaintiff on dual therapy; in fact, Dr. Sherrod commented that it is "pretty standard" and "medically appropriate" to prescribe Plavix and aspirin for Plaintiff's condition. Id., T108:14-109:8.[12]

[12] Nurse Coon was under the supervision of Dr. Sherrod. Without delving into the specifics of her testimony, Nurse Coon's statements regarding the risks of taking Plavix and aspirin, as well as whether dural therapy was the appropriate treatment for Plaintiff at the time, were consistent with those statements made

As this Court has stressed, Texas law is clear on causation: "when the prescribing physician is aware of the product's risks and decides to use it anyway, any inadequacy of the product's warning, as a matter of law, is not the producing cause of the patient's injuries." Centocor, 372 S.W. 3d at 170. Under this scenario, "where a physician testifies that he [or she] was aware of the risks of which plaintiff complains, it is then the plaintiff's burden to prove that a different warning would have changed the physician's decision to prescribe the medication." Id.(citations and quotations omitted). It is clear from the above-testimony of both Drs. McCullough and Sherrod that they were aware of the serious risks of bleeding when placing Plaintiff on dual therapy with Plavix and aspirin.[13] Indeed, the opinions of both doctors

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by Drs. McCullough and Sherrod. See, e.g., Coon's Dep., T58:4-7; T42:13-43:9; T43:23-44:2; T54:3-55:3; T121:16-21.

[13] Plaintiff cites to different parts of Dr. McCullough's deposition and argues that had the doctor known that Plavix was ineffective and of particular risk to Plaintiff, Dr. McCullough would not have prescribed the drug. See Pl. Opp. Br., pp. 19-20. However, not only does the testimony to which Plaintiff refers fail to support his position, Plaintiff misconstrues Dr. McCullough's answers. For example, Plaintiff's counsel asked Dr. McCullough whether it would affect his decision if BMS published information concerning the lack of efficacy of Plavix with the use of stents after one year. During the testimony, the doctor responded that he was not aware of BMS publishing any information on that subject. See McCullough's Dep., T96:2-11. Instead of citing to this answer, Plaintiff, in his Opposition, cites a different part of the doctor's testimony which clearly is not responsive to the question posed. Even more troubling, some of Plaintiff's citations to the testimony are incomplete and thus, misleading. See, e.g., Pl. Opp. Br., p. 19.

were unequivocal: because the medical benefits for Plaintiff's condition outweighed the risks, the physicians were confident that the treatment they had provided for Plaintiff was medically necessary and appropriate. In response, Plaintiff has produced no evidence – testimonial or otherwise – to suggest that a different warning would have led these doctors to alter their treatment for Plaintiff.[14] See Centocor, 372 S.W. 3d at 171. Even more importantly, Drs. McCullough and Sherrod both represented that they would have not changed their prescription for Plaintiff even understanding the additional risks or questions of efficacy Plaintiff has raised in this litigation. Accordingly, because there is no causation evidence to support Plaintiff's failure-to-warn claim, this claim is dismissed.

C. Statutory Rebuttable Presumption – FDA Approved Labels

Plaintiff's failure-to-warn claim fails for the additional reason that, under Texas law, Defendants are presumed not liable because the Plavix warning labels were approved by the FDA. In Texas, where prescription drug manufacturers comply with the FDA regulations, Texas law creates a rebuttable presumption of non-liability in prescription drug suits. See Tex. Civ. Prac. & Rem. Code. Ann. § 82.007; Lofton v. McNeil Consumer & Specialty

[14] Moreover, Plaintiff has not presented any objective evidence that a different warning would have affected the decision of a reasonable doctor to prescribe Plavix and aspirin for Plaintiff's condition.

Pharmaceuticals, 672 F.3d 372, 374 (5th Cir. 2012); Phares v. Actavis-Elizabeth, LLC, No. 11-63, 2012 U.S. Dist. LEXIS 123858, at *17-18 (S.D. Tex. Aug. 30, 2012).

Section 82.007 provides, in relevant part:

> (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:
>
> > (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended; or
> >
> > (2) the warnings provided were those stated in monographs developed by the United States Food and Drug Administration for pharmaceutical products that may be distributed without an approved new drug application.
>
> (b) The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that:
>
> > (1) the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the United States Food and Drug Administration required information that was material and relevant to the performance of the product and was causally related to the claimant's injury . . . ;

Tex. Civ. Prac. & Rem. Code. Ann. § 82.007(a) and (b).

Where a fact is a "presumption" or "presumed," it means that "the trier of fact must presume the existence of the fact unless

and until evidence is introduced to support a finding of its nonexistence." Murthy, 847 F.Supp. 2d at 973(citing Tex. Bus. & Com. Code Ann. § 1.201(b)(29)). Therefore, the effect of a presumption "is to shift the burden of producing evidence to the party against whom it operates." Id. (citations and quotations omitted). In order to rebut the statutory presumption, the plaintiff has to present sufficient evidence to demonstrate that the defendant defrauded the FDA and that the FDA, itself, has also found fraud on the part of the drug manufacturer. Lofton, 672 F.3d at 380.

Here, Plaintiff's Complaint assumes Defendants' warnings complied with the FDA standards. In fact, there is no dispute that the Plavix warnings were approved by the FDA. Although Plaintiff suggests that the FDA has "privately expressed doubts to the Defendants that there is any benefit to Plavix use after three months," see Pl. Opp. Brief, p. 9, Plaintiff presents no evidence, nor does he even argue, that Defendants defrauded the FDA in any way. Moreover, there is no evidence of any kind establishing that the FDA has found fraud on the part of Defendants in connection with the Plavix warning labels. Indeed, the bulk of Plaintiff's case against Defendants is premised upon the fact that there is competing scientific evidence to suggest that Plavix is ineffective under certain circumstances in patients and that there is a substantial risk of bleeding when taking both Plavix and aspirin at

the same time. Absent any evidence to show "fraud on the FDA," Plaintiff fails to rebut the presumption, and such failure is fatal to his failure-to-warn claim. Based on this reason alone, such a claim cannot survive summary judgment. See Phares, 2012 U.S. Dist. LEXIS 123858, at *19-20 ("Since the Texas non-liability presumption applies . . . Plaintiff's failure to warn claims must be dismissed."); Murthy, 847 F. Supp. 2d at 976 (dismissing the plaintiff's failure-to-warn claims since the plaintiff failed to rebut the statutory presumption under § 82.007(a)); Anderson v. Abbott Labs., No.11-1825, 2012 U.S. Dist. LEXIS 141585, at *10-11 (N.D. Tex. Sep. 30, 2012)(same).

Accordingly, Plaintiff failure-to-warn claim is summarily dismissed.

III. Texas Defective Design Claim

Plaintiff concedes that Texas permits a design defect claim only "premised on a failure to warn." Ebel v. Lilly & Co., 536 F.Supp. 2d 767, 773 (S.D. Tex. 2008); Centocor, 372 S.W. 3d at 173; Hackett v. G.D. Searle & Co., 246 F.Supp. 2d 591, 595 (W.D. Tex. 2002) (citing Restatement (Second) Torts § 402A, comment k) (holding that prescription drugs are not susceptible to a design defect claim where, as here, the drug is "accompanied by proper directions and warning."). In this case, having already determined that Plaintiff is unable to establish any triable issue with respect to his failure-to-warn claim, Plaintiff's design claim

correspondingly fails. See Holland v. Hoffman-La Roche, Inc., No. 06-1298, 2007 U.S. Dist. LEXIS 84507, at *8 (N.D. Tex. Nov. 15, 2007).

IV. Texas Manufacturing Defect Claim

To sustain a claim for manufacturing defect, Plaintiff must produce sufficient evidence on this motion to show that by ingesting Plavix, Plaintiff suffered from "a manufacturing flaw which render[ed] the product unreasonably dangerous." Gerber v. Hoffman-La Roche, Inc., 392 F.Supp. 2d 907, 922 (S.D. Tex. 2005)(citation and quotations omitted). In that regard, Plaintiff must prove that the drug deviated "in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous." Ford Motor Co. v. Ridgway, 135 S.W. 3d 598, 600 (Tex. 2004). Here, no such evidence has been adduced by Plaintiff. Indeed, the genesis of Plaintiff's complaints about Plavix is the drug's anti-platelet properties, which allegedly caused him to suffer injuries related to massive bleeding. Those anti-clotting properties are the intended effects of Plavix, and therefore, by Plaintiff's own allegations, the nature of his claim is not premised on whether the drug deviated from the construction or specifications of Plavix. Without any evidence showing that Plavix was defectively manufactured, this claim is dismissed.

V. Negligence Claim

Plaintiff's negligence claim is nothing more than a restatement of his 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." Am. Comp., ¶ 69. Because the Court has found that none of his 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. Aside from Plaintiff's dispute centered around the accuracy of the Plavix warning label, Plaintiff has failed to rebut the statutory presumption of non-liability law. In that connection, because Plaintiff has neither suggested nor provided any evidence that the FDA was defrauded in any way, additional discovery would not cure Plaintiff's deficiencies. Moreover, much of what Plaintiff proposes to seek relates to Plavix's effectiveness, which I have found to be neither relevant nor probative of Plaintiff's claims. Also, Plaintiff has had the opportunity to take the depositions of Plaintiff's treating physicians. As the Court has already found that these physicians' testimonies do not support Plaintiff's claim in light of the

learned intermediary doctrine, additional discovery would not likely lead Plaintiff to any new evidence that would change the results here. Accordingly, Plaintiff's position that the motion is premature and further discovery should be taken is without merit.

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 3, 2013

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