IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

BETTY LOOMIS, as Personal Representative of the Estate of JAMES R. LOOMIS, SR., and individually Plaintiff, v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM INTERNATIONAL GMBH; BOEHRINGER INGELHEIM VETMEDICA, INC.; and BOEHRINGER INGELHEIM USA CORPORATION, Defendants.	)	C.A. No.: N16C-12-282-PRA

Submitted: April 13, 2017
Decided: June 29, 2017

Upon Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corp.'s Motion to Dismiss Plaintiff's Complaint
DENIED

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DAVIS, J.

I. INTRODUCTION

This is a products liability case arising out of the use of the drug Pradaxa. Plaintiff Betty Loomis, as a personal representative of the estate of James Loomis, filed a Complaint (the "Complaint") against Defendants Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer

Pharmaceuticals"), Boehringer Ingelheim International GmBH ("Boehringer International"), Boehringer Ingelheim Vetmedica, Inc. ("Boehringer Vetmedica"), and Boehringer Ingelheim USA Corp. ("Boehringer USA") (collectively, the "Defendants"). The Complaint asserts causes of action for: (i) Strict Liability, (ii) Strict Liability – Design Defect, Marketing Defect and Manufacturing Defect, (iii) Negligence, (iv) Breach of Express Warranty, (v) Breach of Implied Warranty, (vi) Wrongful Death, and (vii) Loss of Consortium.

On February 16, 2017, Defendants Boehringer Pharmaceuticals and Boehringer USA (together, "the Boehringer Defendants") moved to dismiss the Complaint and filed Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corp.'s Motion to Dismiss Plaintiff's Complaint (the "Motion to Dismiss").[1] The Boehringer Defendants contend that the allegations in the Complaint about the lack of a reversal agent fail to state a claim for relief because the Food and Drug Administration ("FDA") approved a reversal agent before the date of Mr. Loomis' injuries. Mrs. Loomis opposes the Motion to Dismiss, responding to the Motion to Dismiss with Plaintiff's Opposition to Defendants' Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corp.'s Motion to Dismiss Plaintiff's Complaint (the "Response") on March 31, 2016.

The Court held a hearing and heard oral argument on the Motion to Dismiss on April 7, 2017. At the conclusion of the hearing, the Court asked the parties to submit additional briefing on the learned intermediary doctrine, which the Boehringer Defendants raised for the first time at the hearing. On April 13, 2017, the Boehringer Defendants filed Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corp.'s Supplemental Brief in Support of its Motion to Dismiss Plaintiffs' Complaints Pursuant to Rule 12(b)(6) (the

[1] The other named Defendants, Boehringer Vetmedica and Boehringer International, do not appear or join the Motion to Dismiss. The Boehringer Defendants represent in the Motion to Dismiss that these additional defendants have not yet been served. Defs.' Mot. at p. 1, fn. 1.

"Supplemental Motion")[2] and Ms. Loomis' counsel filed Plaintiff's Letter Brief in Further Opposition to Defendants' Motion to Dismiss Plaintiff's Complaint (the "Supplemental Response"). After receiving the Supplemental Motion and the Supplemental Response, the Court took the Motion to Dismiss under advisement.

This is the Court's decision on the Motion to Dismiss. For the reasons set forth below, the Court **DENIES** the Motion to Dismiss.

II. FACTUAL BACKGROUND[3]

Mrs. Loomis, personal representative of the estate of decedent Mr. Loomis, is an individual and resident of the State of California and is the spouse of decedent Mr. Loomis.[4] Boehringer Pharmaceuticals, Boehringer USA, and Boehringer Vetmedica are Delaware corporations doing business in Delaware.[5] Boehringer International is a foreign corporation with a principal place of business in Rhein, Germany.[6]

Defendants were involved in the manufacturing, marketing, advertising, and distribution of the drug Pradaxa.[7] Pradaxa is a blood-thinning medication used to reduce the risk of stroke and blood clots in certain individuals.[8] Pradaxa was approved by the FDA on October 19, 2010, making it the first new treatment alternative to Coumadin.[9] Prior to FDA approval, Coumadin

[2] The Supplemental Motion addresses issues raised in this case and a related case (C.A. No. N16C-12-231-PRA) before the Court involving the same Defendants.
[3] As the Motion to Dismiss is a motion filed under Superior Court Civil Rule 12 ("Civil Rule __"), the Court will, unless otherwise indicated, be using the facts as alleged in the Complaint ("Pl.'s Compl."). *See, e.g., Central Mortg. Co. v. Morgan Stanley Mortg. Capital Holdings LLC*, 27 A.3d 531, 536 (Del. 2011)
[4] Pl.'s Compl. ¶ 1.
[5] *Id.* ¶¶ 4, 6–7.
[6] *Id.* ¶ 5.
[7] *Id.* ¶ 8.
[8] *Id.* ¶ 9.
[9] *Id.* ¶ 10.

was the only oral anticoagulation available in the U.S. for reducing stroke and systemic embolism in patients with atrial fibrillation.[10]

After FDA approval, Defendants promoted Pradaxa as a viable alternative to Coumadin in patients with atrial fibrillation.[11] Defendants' marketing campaign emphasized that Pradaxa, unlike Coumadin, did not require blood monitoring, dose adjustment, or changes to diet.[12] Pursuant to this marketing campaign, Mr. Loomis' doctors received promotional materials from Defendants, and Mr. Loomis also received direct-to-consumer advertisements.[13] Based on the information contained in these promotional materials, Mr. Loomis began taking Pradaxa for atrial fibrillation and heart problems on April 21, 2011.[14] Subsequently, Mr. Loomis suffered subarachnoid hemorrhage on December 5, 2015 and was admitted to the hospital in Nashville, Tennessee.[15] Mr. Loomis died on December 23, 2015.[16]

On December 21, 2016, Mrs. Loomis filed the Complaint against Defendants. In short, the Complaint alleges that through their marketing campaign, Defendants' overstated the efficacy of Pradaxa with respect to preventing stroke and systemic embolism, failed to adequately disclose to or warn patients that there is no drug or means to reverse the anticoagulation effects of Pradaxa, and that such irreversibility could have permanently disabling, life-threatening and fatal consequences" such as increased risk of bleeding.[17] The Complaint further alleges that the Defendants' actions directly and proximately caused Mr. Loomis' injuries.[18]

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[10] *Id.* ¶ 11.
[11] *Id.* ¶ 12.
[12] *Id.*
[13] *Id.* ¶¶ 18, 21.
[14] *Id.* ¶¶ 21, 56.
[15] *Id.* ¶ 58.
[16] *Id.*
[17] *Id.* ¶ 16.
[18] *Id.* ¶¶ 52, 59–60.

III. PARTIES' CONTENTIONS

A. THE BOEHRINGER DEFENDANTS

The Boehringer Defendants contend that the main claim in the Complaint—that Pradaxa was defective because it contained no reversal agent—does not state a claim for relief because the FDA approved a reversal agent for Pradaxa on October 23, 2015, two months before Mr. Loomis' hemorrhage on December 5, 2015. The Boehringer Defendants further argue that whether Mr. Loomis knew about the reversal agent is irrelevant because the Boehringer Defendants had no duty to warn Mr. Loomis about the reversal agent based on Tennessee's learned intermediary doctrine.

B. MRS. LOOMIS

Mrs. Loomis claims that the Complaint is properly pleaded because it is not based exclusively on the lack of a reversal agent as argued by the Boehringer Defendants. Rather, the Complaint also includes allegations related to the efficacy of Pradaxa and the Boehringer Defendants' failure to warn of the risks associated with the use of Pradaxa. Mrs. Loomis further argues that it is a question of fact whether the Boehringer Defendants had a duty to warn under the learned intermediary doctrine. In the alternative, Mrs. Loomis also asks for leave to amend under Civil Rule 15(a) the Complaint if the Court does not find Mrs. Loomis' arguments to be persuasive.[19]

IV. LEGAL STANDARD

Upon a motion to dismiss under Civil Rule 12(b)(6), the Court (i) accepts all well-pleaded factual allegations as true, (ii) accepts even vague allegations as well-pleaded if they give the opposing party notice of the claim, (iii) draws all reasonable inferences in favor of the non-moving party, and (iv) only dismisses a case where the plaintiff would not be entitled to

[19] Pl.'s Resp. at p. 7.

recover under any reasonably conceivable set of circumstances.[20] However, the Court must "ignore conclusory allegations that lack specific supporting factual allegations."[21]

V. DISCUSSION

A. THE COMPLAINT STATES MULTIPLE CLAIMS FOR RELIEF, INCLUDING A DESIGN DEFECT CLAIM BASED ON THE LACK OF A REVERSAL AGENT

The Boehringer Defendants first argue that the Complaint's allegations about the lack of a reversal agent fail to state a claim upon which relief can be granted because the FDA approved a reversal agent before the date of Mr. Loomis' injuries. To make this argument, the Boehringer Defendants contend that the Complaint is premised entirely on the allegations about the reversal agent. The Court finds that the Complaint alleges more than the lack of a reversal agent. The Complaint contains multiple contentions, in addition to those concerning the reversal agent, that are sufficient at this early stage in the proceeding to sustain Mrs. Loomis' claims.

One of the Complaint's principal claims is for design defect. The Court agrees that one of the allegations pleaded to support this claim is that there lacked a reversal agent to reverse the anticoagulation effects of Pradaxa. However, the Court notes that this is not the only allegation raised in the Complaint. For example, one of the Complaint's chief allegations relates to Defendants' duty to warn. The Complaint asserts that Defendants had a duty to warn of the risks associated with Pradaxa, and that Defendants breached that duty by failing to provide adequate warnings about the safety and side effects of Pradaxa.[22] Specifically, the Complaint states that Defendants failed to warn about the lack of a reversal agent, the anticoagulation effects of Pradaxa, the increased risk of bleeding in Pradaxa users, and the increased risk of gastrointestinal

[20] *See Central Mortg. Co. v. Morgan Stanley Mortg. Capital Holdings LLC*, 27 A.3d 531, 536 (Del. 2011); *Doe v. Cedars Academy*, No. 09C-09-136, 2010 WL 5825343, at *3 (Del. Super. Oct. 27, 2010).
[21] *Ramunno v. Crawley*, 705 A.2d 1029, 1034 (Del. 1998).
[22] Pl.'s Compl. ¶¶ 28–31; 66–68, 91–92.

bleeding in Pradaxa users.[23] This failure to warn included Defendants' failure to include a "boxed warning" and a "bolded warning" about the bleeding events associated with Pradaxa.[24] The Complaint also alleges that Defendants misrepresented the efficacy of Pradaxa through its marketing campaigns and promotional materials, as well as failed to research, study, and investigate the safety profile of Pradaxa.[25]

Based on the foregoing, the Court cannot agree with the Boehringer Defendants' argument that that the Complaint is premised entirely on the allegations about the reversal agent. If the allegations regarding the reversal agent are removed from the Complaint, multiple allegations regarding the Boehringer Defendants' negligence and alike remain, principally the allegation regarding the Boehringer Defendants' duty and failure to warn. Under these circumstances, and in interpreting the inferences to be drawn from the facts in the light most favorable to Mrs. Loomis, dismissal of the case in its entirety is not justified.

B. THE RECORD IS TOO UNDERDEVELOPED TO FIND THAT THE BOEHRINGER DEFENDANTS HAD NO DUTY TO WARN UNDER THE LEARNED INTERMEDIARY DOCTRINE

Even if the FDA approved a reversal agent before Mr. Loomis' injuries, Mrs. Loomis argues that there are still questions of fact precluding dismissal, such as whether Mr. Loomis or his physician had actual knowledge of Pradaxa's design defects and the newly-approved reversal agent. In response, the Boehringer Defendants contend that Mr. Loomis' actual or subjective knowledge is irrelevant to the claims in this case because, under Tennessee's learned intermediary doctrine, the Boehringer Defendants had no duty to warn about Pradaxa's design defects or alike. At this early stage of the case, the Court finds that the record is too

[23] *Id.* ¶¶ 31, 34, 35, 70, 91–92.
[24] *Id.* ¶¶ 36–37.
[25] *Id.* ¶¶ 12–20, 28–29.

underdeveloped to rule that the Boehringer Defendants had no duty to warn under the learned intermediary doctrine.

The Supreme Court of Tennessee in *Pittman v. Upjohn Co.*[26] set forth an objective standard by which to evaluate a drug manufacturer's duty to warn.[27] Under the "learned intermediary doctrine," manufacturers of unavoidably unsafe products who have a duty to give warnings may "reasonably rely on intermediaries to transmit their warnings and instruction."[28] Physicians qualify as such intermediaries based on the "pivotal role they play in the unique system used to distribute prescription drugs."[29] However, the *Pittman* court set forth an important qualification for when a physician can act as an intermediary.[30] Physicians can be learned intermediaries only after they have received adequate warnings from the manufacturer.[31] This means that a drug manufacturer is shielded from liability only when the warnings are adequate; "the learned intermediary doctrine does not shield a drug manufacturer from liability for inadequate warnings to the physician."[32]

Pittman expanded upon what constitutes an adequate warning.[33] *Pittman* stated that prescription drug warnings are adequate when they contain a "full and complete disclosure of the potential adverse reactions to the drug."[34] The adequacy of prescription drug warnings also depends on the expertise of the users of the product.[35] *Pittman* explained that "where a product is marketed solely to professionals experienced in using the product, such as physicians, the

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[26] 890 S.W.2d 425 (Tenn. 1994).
[27] *Pittman*, 890 S.W.2d at 429. Other jurisdictions also recognize this objective standard for analyzing a drug manufacturer's duty to warn. *See Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1115 (4th Cir. 1988); *Guevara v. Dorsey Laboratories*, 845 F.2d 364, 367 (1st Cir. 1988); *Stone v. Smith, Kline & French Laboratories*, 731 F.2d 1575, 1579–80 (11th Cir. 1984); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir. 1974).
[28] *Pittman*, 890 S.W.2d at 429.
[29] *Id.*
[30] *See id.*
[31] *Id.* (citing *Amore v. G.D. Searle & Co.*, 748 F.Supp. 845, 850 (S.D. Fla. 1990)).
[32] *Pittman*, 890 S.W.2d at 429.
[33] *See id.*
[34] *Id.*
[35] *Id.* at 430.

manufacturer may rely on the knowledge that a reasonable professional would apply in using the product."[36] In the end, *Pittman* held that the adequacy of a drug manufacturer's warning is a question of fact, and it becomes a question of law only when the instructions are "accurate and unambiguous."[37]

The Court finds that the Boehringer Defendants cannot yet rely on the learned intermediary doctrine to have the Complaint dismissed. The question of the adequacy of the warnings is disputed by the parties.[38] Mrs. Loomis contends that the Boehringer Defendants failed to provide adequate warnings and misrepresented the nature and side effects associated with Pradaxa use. The Boehringer Defendants claim their warnings were adequate and that Pradaxa's label was updated to include information about the lack of a reversal agent.

There is insufficient evidence before the Court to resolve the parties' dispute. On the present record, there is no evidence regarding what warnings, if any, Mr. Loomis' physician received. Unlike in *Pittman*, there is no evidence of any conversations between the Boehringer Defendants and Mr. Loomis' physician or any literature provided to Mr. Loomis' physician. There is also no evidence showing that the Boehringer Defendants provided instructions to Mr. Loomis' physician regarding the use, safety, and side effects of Pradaxa. Finally, there is no evidence regarding when Pradaxa's label was purportedly updated and when, if ever, Mr. Loomis or his physician received notice of this change. The record is simply too underdeveloped to allow the Court to engage in any meaningful analysis of the warnings provided in this case.

Without a determination on the adequacy of the warnings, the Court cannot find that Mr. Loomis' physician was a learned intermediary or that the learned intermediary doctrine applies.

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[36] *Id.*
[37] *Id.*
[38] *See Adkins v. Bristol-Myers Squibb Co.*, C.A. No. 3:07-CV-00901, 2009 WL 5216986, at *8 (D.N.J. Dec. 30, 2009) (rejecting defendant manufacturer's motion to dismiss based on the learned intermediary doctrine because the parties disputed the adequacy of the warnings provided to plaintiff's physician).

This is not to say that the Court is foreclosed from revisiting this issue prior to trial once the parties develop the record through discovery. On the contrary, if the parties engage in discovery, the Court may be in a better position to analyze the adequacy of the warnings given by the Boehringer Defendants. The Court cannot, however, based on the underdeveloped record before it, dismiss the case against the Boehringer Defendants.

VI. CONCLUSION

For the reasons set forth above, the Court will **DENY** Defendants Boehringer Ingelheim Pharmaceuticals, Inc. and Boehringer Ingelheim USA Corp.'s Motion to Dismiss Plaintiff's Complaint.

IT IS SO ORDERED.

Dated: June 29, 2017
Wilmington, Delaware

/s/ Eric M. Davis
Eric M. Davis, Judge