UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

FRANK FITZGIBBONS, Individually And as Special Administrator for the Estate of Bonnie Fitzgibbons	)	No., 3:12-cv-00614-DRH-SCW
Plaintiff,	)	
v.	)	
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC. *et al.*,	)	
Defendants.		

ORDER DENYING MOTION TO DISMISS

Herndon, Chief Judge

I. INTRODUCTION

The above referenced diversity case is before the Court on the defendant's, Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI'), motion to dismiss the plaintiff's claims for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons set forth below, the motion is **DENIED**.

II. PROCEDURAL BACKGROUND

A. Overview of Related Pradaxa Product Liability Litigation

The above referenced case involves PRADAXA ("Pradaxa"), a prescription pharmaceutical indicated for the prevention of stroke and systemic embolism (blood clots) in patients with abnormal heart rhythm (atrial fibrillation). The plaintiff in the above referenced case alleges that, as a result of ingesting Pradaxa,

the plaintiff's decedent, Bonnie Fitzgibbons, suffered a serious bleeding event leading to hospitalization and death. Presently, there are at least 36 cases involving Pradaxa with substantially similar fact patterns and allegations ("Pradaxa Product Liability Cases") pending in fourteen different judicial districts in the United States. *See* MDL No. 2385, *In re Pradaxa Prod. Liab. Litig.* (Doc. 54).[1] Of the 36 Pradaxa Product Liability Cases pending in federal court, 17 are on file in this judicial district and have been assigned to the undersigned judge.[2]

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[1] On June 21, 2012, various Boehringer entities filed their response to the MDL Motion. As of the date of that response, at least 30 Pradaxa Product Liability Cases were pending in 14 different federal judicial districts. At that time, 11 of the 30 cases were pending in the Southern District of Illinois. *See* MDL No. 2385, *In re Pradaxa Prod. Liab. Litig.* (Doc. 54). Since the filing of that response, 6 additional Pradaxa Product Liability Case have been filed with this Court *See Witt v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.,* No. 3:12-cv-781; *McCoy et al v. Boehringer Ingelheim Pharmaceuticals, Inc. et al*, No. 3:12-cv-806; *Bishop et al v. Boehringer Ingelheim Pharmaceuticals, Inc. et al*, No. 3:12-cv-810; *Elahee et al v. Boehringer Ingelheim Pharmaceuticals, Inc. et al* No. 3:12-cv-811; *Martin v. Boehringer Ingelheim Pharmaceuticals, Inc. et al*; No. 3:12-cv-812; *Schofield v. Boehringer Ingelheim Pharmaceuticals, Inc. et al*; No. 3:12-cv-813. Accordingly, there are now at least 36 Pradaxa Product Liability Cases pending in federal district courts across the country and 17 of those cases are pending in this judicial district.

[2] The following 17 cases, filed in the Southern District of Illinois, involve Pradaxa and include substantially similar product liability claims: (1) *Boston v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.*, No. 3:12-cv-610; (2) *Richardson v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.*, No. 3:12-cv-611; (3) *Garner v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.*, No. 3:12-cv-612; (4) *Herbeck v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.*, No., 3:12-cv-613; (5) *Fitzgibbons v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.*, No., 3:12-cv-614; (6) *Sellers v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.*, No., 3:12-cv-615; (7) *Smith v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.*, 3:12-cv-616; (8) *Stout v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.*, No. 3:12-cv-617; (9) *Kekich v. Boehringer Ingelheim Pharmaceuticals Inc. et al.,* No. 3:12-cv-709; (10) *Crosby v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.,* No. 3:12-cv-710; (11) *Williams v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.,* No. 3:12-cv-711; (12) *Witt v. Boehringer Ingelheim Pharmaceuticals,*

On May 31, 2012, plaintiff Vera Sellers (*Sellers v. Boehringer Ingelheim Pharmaceuticals, Inc. et al.*, No. 3:12-615) filed a motion for transfer of actions pursuant to 28 U.S.C. § 1407 ("MDL Motion"). *See Id.* The MDL Motion requests centralization and consolidation of the Pradaxa Product Liability Cases before a single federal district court. *Id.* Plaintiff Sellers' proposed forum is the Southern District of Illinois. *Id.* On May 30, 2012, five of the entities named as defendants in the Pradaxa Product Liability Cases filed a response to the MDL Motion. *See* MDL No. 2385, *In re Pradaxa Prod. Liab. Litig.* (Doc. 54). The responsive pleading states that these defendants are not opposed to consolidation but are opposed plaintiff Sellers' proposed forum. *Id.* These defendants propose consolidation in the District of Connecticut or, alternatively, the Eastern District of Tennessee or Eastern District of Kentucky. *Id.* The Judicial Penal on Multidistrict Litigation ("JPML") will hear the MDL Motion on July 26, 2012.

B. Effect of Pending MDL Motion

The pendency of a motion for consolidation "does not affect or suspend orders and pretrial proceedings in any pending federal district court action and does not limit the pretrial jurisdiction of that court." J.P.M.L. Rule 2.1(d). Further, this Court recently concluded that a stay of pretrial proceedings is not

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Inc. et al., No. 3:12-cv-781; (13) *McCoy et al v. Boehringer Ingelheim Pharmaceuticals, Inc. et al*, No. 3:12-cv-806; (14) *Bishop et al v. Boehringer Ingelheim Pharmaceuticals, Inc. et al*, No. 3:12-cv-810; (15) *Elahee et al v. Boehringer Ingelheim Pharmaceuticals, Inc. et al* No. 3:12-cv-811; (16) *Martin v. Boehringer Ingelheim Pharmaceuticals, Inc. et al*; No. 3:12-cv-812; and (17) *Schofield v. Boehringer Ingelheim Pharmaceuticals, Inc. et al*; No. 3:12-cv-813.

warranted in the Pradaxa Product Liability Cases pending in this Court. Accordingly, the Court proceeds with the subject motion to dismiss.

C. This Order Addresses BIPI's Motion to Dismiss the Plaintiff's Claims Pursuant to Rule 12(b)(6)

In addition to suing BIPI, the U.S. distributor of Pradaxa, the plaintiff also sued three other entities, Boehringer Ingelheim USA Corporation ("BI USA"), Boehringer Ingelheim Corporation ("BIC"), and Boehringer Ingelheim Vetmedica, Inc. ("BIVI"). BI USA, BIC, and BIVI filed separate motions to dismiss (or in the alternative for summary judgment) arguing that they have no involvement with the design, manufacture, marketing, sale, labeling, promotion, or any other aspect of Pradaxa. Shortly thereafter, on July 20, 2012, the Court granted voluntary dismissal without prejudice as to BI USA, BIC, and BIVI. Accordingly, the claims against these entities are no longer in issue. In light of these dismissals, the Court reviews the allegations in the plaintiff's complaint directed at "defendants" generally to refer only to BIPI.

III. RELEVANT FACTUAL BACKGROUND

A. Legal Standard

When the court acts on a defendant's motion to dismiss pursuant to Rule 12(b)(6), the court accepts as true all well-pled factual allegations and draws all reasonable inferences in the plaintiff's favor. *See Rujawitz v. Martin*, 561 F.3d 685, 688 (7th Cir. 2009); *St. John's United Church of Christ v. City of Chicago,* 502 F.3d 616, 625 (7th Cir. 2007), *cert. denied,* 553 U.S. 1032, 128 S.Ct. 2431,

171 L.Ed.2d 230 (2008). Generally, the Court's analysis is limited to factual allegations contained in the complaint and the complaint's exhibits. *See* Fed. R. Civ. P. 12(d) (documents outside the complaint may not be considered without converting the motion to dismiss into a motion for summary judgment).

There are, however, two exceptions to this general rule: First, a district court may "take judicial notice of matters of public record without converting a motion for failure to state a claim into a motion for summary judgment." *Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1080 (7th Cir. 1997). Second, a court may consider documents attached to a motion to dismiss * * * if they are referred to in the plaintiff's complaint and are central to his claim." *Brownmark Films, LLC v. Comedy Partners*, ––– F.3d ––––, 2012 WL 2044806, at *2 (7th Cir.2012) (internal quotation omitted).

With the exception of the text of the warning that has always accompanied Pradaxa, the facts below are taken from the plaintiff's complaint, which at this point in the litigation the Court presumes to be true. Additionally, the Court considers the text of the warning that has always been included in Pradaxa's labeling and prescribing information. Although the exact language of the subject warning is not included in the plaintiff's complaint, it may be considered by the

Court without converting BIPI's motion to dismiss into a motion for summary judgment pursuant to either of the exceptions described above.[3]

B. Relevant Facts

1. Overview

On or about August 2011, the decedent's physician prescribed the prescription drug Pradaxa for treatment of the decedent's non-valvular atrial fibrillation. *Id*. at ¶ 43. Pradaxa is a member of a class of anticoagulants known as direct thrombin inhibitors and is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (patients with atrial fibrillation have an increased risk of stroke). *Id.* at ¶¶ 14-15. Shortly after being prescribed Pradaxa, on or about September 11, 2011, the decedent suffered a severe gastrointestinal bleed causing her to be hospitalized until she died on October 7, 2011. *Id*. During this time, the decedent allegedly experienced excessive and/or uncontrollable bleeding. *Id*. The Pradaxa prescribed to and ingested by the decedent was allegedly "designed, manufactured, marketed, advertised, distributed, promoted, labeled, tested and sold" by BIPI. *Id*. at ¶ 13.

The plaintiff contends, *inter alia*, that despite being aware of certain safety risks associated with use of Pradaxa, BIPI failed to adequately warn or disclose

[3] The text of the subject warning is the basis for one of the arguments raised by BIPI in its motion to dismiss. Specifically, BIPI asserts that the plaintiff's claims are subject to dismissal because the Pradaxa label explicitly warned about the risk of "serious and, sometimes, fatal bleeding." Accordingly, for purposes of addressing this argument, the Court considers the text of the subject warning.

information about such risks to the medical community and consumers.[4] *See e.g., Id.* at ¶ 29(n). Specifically, the plaintiff contends that (1) BIPI failed to adequately warn or disclose information regarding the risk of serious and sometimes fatal irreversible bleeding events associated with the use of Pradaxa; (2) failed to warn or disclose information regarding the protocol, or lack thereof, for reducing the anticoagulation effects of Pradaxa in patients who experience a severe bleeding incident; (3) failed to provide adequate warnings and information regarding the increased risks of bleeding in certain patient populations; (4) failed to provide adequate warnings and information regarding the ability or need to assess certain factors in patients taking Pradaxa; and (5) failed to warn that patients taking Pradaxa are at an increased risk for excessive and/or uncontrollable bleeding. *See e.g., Id.* at ¶¶ 21, 23, 24, 25, 29, 54. The plaintiff also contends that BIPI made affirmative misrepresentations regarding the efficacy, safety risk profile, and additional benefits of Pradaxa. *See e.g., Id.* at ¶¶

[4] The plaintiff's complaint includes a number of allegations regarding specific events relating to Pradaxa's risk and safety profile that allegedly provided BIPI with notice of deficiencies in Pradaxa. For events that allegedly occurred prior the decedent receiving a prescription for Pradaxa *see* Doc. 2 at ¶ 26 (adverse events reported between October 2010 and March 2011); ¶ 27 (adverse Medwatch reports filed with the FDA in April, May, and June 2011); ¶ 30 (approval of Pradaxa in New Zealand which imposed lower dosage requirements for patients over 80 years of age and for patients with renal impairment); ¶ 31 (study regarding the risks of Pradaxa use in elderly patients). For events that allegedly occurred at the time of prescription up until the decedent's death *see* ¶¶ 32-33 (requirements imposed by officials in Japan, including a "BOXED WARNING" regarding the risk of severe hemorrhages); ¶ 34 (New Zealand officials report that Pradaxa has a higher incidence of bleeding than Warfarin and a publication in New Zealand stating that the serious risks of Pradaxa, such as lack of an effective reversal agent or protocol, are not fully appreciated by the medical community). The other events identified in the complaint occurred after the decedent's death.

21, 23, 24, 29. Finally, the plaintiff contends that BIPI failed to adequately research or investigate the safety profile of Pradaxa and failed to adequately research or investigate patient weight as a variable factor in establishing recommended dosages of Pradaxa. *Id.* at ¶ 29(c),(d).

The alleged inadequacies and affirmative misrepresentations were reportedly included in the Pradaxa Marketing Campaign and in Pradaxa's labeling and prescribing information. *See Id.* at ¶¶ 17-29. Both decedent and her prescribing physician allegedly relied on information disseminated by BIPI via the Pradaxa Marketing Campaign and/or the information published in Pradaxa's labeling and prescribing information. *Id.* at ¶¶ 22, 42, As to the decedent's prescribing physician, the decision to prescribe Pradaxa was based on information published in Pradaxa's labeling and prescribing materials, information published in Pradaxa's marketing materials, and information provided by BIPI sales representatives. *Id.* at ¶¶ 23, 42, 46.[5] Neither the decedent nor her prescribing physician knew or could have known that ingesting Pradaxa would expose the decedent to the risk of an irreversible bleeding event (and other safety risks that BIPI allegedly failed to adequately disclose) or that the purported additional benefits of Pradaxa had been misrepresented. *Id.* at ¶ 42, 46. If the

[5] The decedent's prescribing physician allegedly received marketing materials and information from BIPI sales representatives that promoted Pradaxa as being more effective and convenient than Warfarin. Purportedly, the marketing information the prescribing physician received failed to disclose that there was no effective reversal agent or protocol for controlling bleeding in patients taking Pradaxa. *Id.* at ¶ 23.

decedent or her prescribing physician had known the truth about Pradaxa and if Pradaxa had contained adequate warnings, the decedent would not have used Pradaxa.

A more detailed review of the plaintiff's assertions regarding the Pradaxa Marketing Campaign and Pradaxa's labeling and prescribing information is included below.

2. The Pradaxa Marketing Campaign

The U.S. Food and Drug Administration ("FDA") approved Pradaxa for use in the United States in October 2010. *Id*. ¶ 15. In 2010 and 2011 BIPI marketed and promoted Pradaxa ("Pradaxa Marketing Campaign"). *Id.* at ¶¶ 17-19. BIPI's marketing efforts included, *inter alia*, "detailing sessions" (marketing/sales visits by BIPI representatives) with primary care physicians and other healthcare professionals. *Id.* at ¶ 19. It also included direct to consumer advertisements. *Id.* at 20. The Pradaxa Marketing Campaign allegedly overstated the effectiveness and benefits of Pradaxa. Specifically, the plaintiff alleges, the marketing campaign overstated the efficacy of Pradaxa with respect to preventing stroke and systemic embolism. *Id.* at ¶¶ 21, 23. The plaintiff also contends the Pradaxa marketing campaign improperly promoted Pradaxa as being more effective and convenient than the prescription anticoagulant Warfarin.[6] *Id.* at ¶ 17.

[6] Prior to Pradaxa, Warfarin was the only oral anticoagulant available in the United States for reducing the risk of stroke and systemic embolism in patients with atrial fibrillation. *Id*. at ¶ 16.

Like Pradaxa, Warfarin is a prescription anticoagulant indicated for reducing the risk of stroke and systemic embolism in patients with atrial fibrillation. *Id*. at ¶ 16. Patients taking Warfarin must follow dietary restrictions and regularly monitor their blood levels to determine whether their dosage should be adjusted. *Id*. Patients taking Pradaxa, on the other hand, are not under any dietary restrictions and do not have to undergo regular blood testing. *Id*.

An additional difference between Pradaxa and Warfarin is the availability of a reversal agent or protocol for the drugs' anticoagulation effects. *Id*. at ¶ 24. With regard to Warfarin, there is an established protocol for treating and stabilizing patients who experience a serious bleeding event while taking the drug. As to Pradaxa, there is no effective means for reversing the anticoagulation effects of the drug in patients who experience a serious bleeding event. *Id.* at ¶¶ 21, 23, 24. Therefore, there is no effective means to treat and stabilize patients who experience a serious bleeding event while taking Pradaxa. *Id*. at ¶¶ 21, 23, 24.

The plaintiff alleges that the Pradaxa Marketing Campaign failed to disclose information regarding the lack of a reversal agent or protocol for reversing the anticoagulation effects of Pradaxa. *Id*. The plaintiff also alleges that the Pradaxa Marketing Campaign failed to adequately disclose other risks and safety information associated with the use of Pradaxa.

3. Pradaxa's Labeling and Prescribing Information

The "Warnings Section" in Pradaxa's labeling and prescribing information has always included the following warning:

> **WARNINGS AND PRECAUTIONS**
>
> Risk of bleeding: PRADAXA can cause serious and, sometimes, fatal bleeding. Promptly evaluate signs and symptoms of blood loss. (5.1).[7]

Plaintiff asserts that Pradaxa's "original"[8] labeling and prescribing information did not include information regarding the protocol, or lack thereof, for reversing the anticoagulation effects of Pradaxa in patients who experience a severe bleeding event. *Id.* at ¶¶ 25, 29(a),(b),(m). Further, the plaintiff contends, it did not disclose that, if serious bleeding were to occur, the lack of an effective reversal agent or protocol could have "permanently disabling, life-threatening or fatal consequences." *Id.* at ¶ 29(m). In addition to failing to disclose the

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[7] The FDA-approved Pradaxa labels are available on the FDA's public website as follows:
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails
(last accessed July 20, 2012).

[8] The plaintiff makes assertions regarding Pradaxa's "original" labeling and prescribing information but does not expressly define the term "original." Other factual allegations in the complaint, however, allow for the Court to reasonably infer (as is required at this stage of the litigation) that the term "original" refers to the labeling and prescribing information that was effective between October 2010 (when Pradaxa was approved by the FDA) and March 2011 (Pradaxa's first labeling modification). As noted above, however, the March 2011 modification did not alter Pradaxa's Warnings Section and allegedly contained the same inadequacies as the original labeling and prescribing information.

information described above, the plaintiff alleges that the original labeling and prescribing information contained the following inadequacies:

- failed to provide adequate warnings or information about the "true safety risks" associated with Pradaxa use;
- failed to provide adequate warnings or information about the problems associated with assessing the degree and/or extent of anticoagulation in patients taking Pradaxa;
- failed to provide adequate warnings or information about the protocol for intervening or stabilizing patients who suffer from bleeding while taking Pradaxa;
- failed to provide adequate warnings or information about the need to assess renal functioning prior to starting a patient on Pradaxa and the need to continue assessing renal functioning while a patient is taking Pradaxa;
- failed to provide adequate warnings or information about the increased risk of bleeding events associated with aging patient populations;
- failed to provide adequate warnings or information about the increased risk of gastrointestinal bleeds in patients taking Pradaxa and specifically in patients with a history of gastrointestinal issues.
- failed to "investigate, research, study and consider, fully and adequately patient weight as a variable factor in establishing recommended dosages of Pradaxa;

- failed to investigate, research, study and define, fully and adequately, the safety profile of Pradaxa;
- failed to include a "Boxed Warning" or a "Bolded Warning" about serious bleeding events associated with Pradaxa use.

Id. at ¶ 29.

In March 2011, BIPI modified Pradaxa's labeling and prescribing information. *Id.* at ¶ 29(n). The next modification to Pradaxa's labeling and prescribing information occurred in November 2011 (after the decedent was prescribed Pradaxa and after the decedent's death).[9] Thus, in the instant case, the relevant information is the information included in the "original" labeling and prescribing material and/or in the March 2011 labeling and prescribing material.

The March 2011 modification provided additional information regarding the use of Pradaxa in patients taking certain medications. The text of the Warnings Section (provided above) remained the same. Further, the plaintiff contends Pradaxa's March 2011 labeling and prescribing information suffered from the same deficiencies as Pradaxa's original labeling and prescribing information. *Id*. at ¶ 29(n).

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[9] Pursuant to the plaintiff's complaint, the Pradaxa labeling and prescribing information was also modified in November 2011 (additional information regarding the use of Pradaxa in patients with kidney disease), January 2012 (nature of revision not specified), and April 2012 (nature of revision not specified).[9] *Fitzgibbons*. at ¶¶ 35, 38, 40. None of the modifications altered the text of the warnings section. The plaintiff alleges that all of the modified labeling and prescribing information suffered from the same deficiencies as the original labeling and prescribing information.

IV. RELEVANT LEGAL PRINCIPLES

A 12(b)(6) motion challenges the sufficiency of the complaint to state a claim upon which relief can be granted. *Hallinan v. Fraternal Order of Police Chicago Lodge 7*, 570 F.3d 811, 820 (7th Cir.), *cert. denied,* —— U.S. ——, 130 S.Ct. 749, 175 L.Ed.2d 517 (2009). The United States Supreme Court explained in *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007), that Rule 12(b)(6) dismissal is warranted if the complaint fails to set forth "enough facts to state a claim to relief that is plausible on its face."

In making this assessment, the district court accepts as true all well-pled factual allegations and draws all reasonable inferences in the plaintiff's favor. *See* Rujawitz v. Martin, 561 F.3d 685, 688 (7th Cir. 2009); *St. John's United Church of Christ v. City of Chicago,* 502 F.3d 616, 625 (7th Cir. 2007), *cert. denied,* 553 U.S. 1032, 128 S.Ct. 2431, 171 L.Ed.2d 230 (2008).

Even though *Twombly* (and *Ashcroft v. Iqbal,* 556 U.S. 662, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)) retooled federal pleading standards, notice pleading remains all that is required in a complaint. "A plaintiff still must provide only 'enough detail to give the defendant fair notice of what the claim is and the grounds upon which it rests and, through his allegations, show that it is plausible, rather than merely speculative, that he is entitled to relief.' " *Tamayo v. Blagojevich,* 526 F.3d 1074, 1083 (7th Cir. 2008). The level of detail the

complaint must furnish can differ depending on the type of case before the Court. So for instance, a complaint involving complex litigation (antitrust or RICO claims) may need a "fuller set of factual allegations ... to show that relief is plausible." *Tamayo,* 526 F.3d at 1083, *citing Limestone Dev. Corp. v. Village of Lemont, Illinois,* 520 F.3d 797, 803–04 (7th Cir. 2008).

The Seventh Circuit Court of Appeals has offered further direction on what (post- *Twombly & Iqbal*) a complaint must do to withstand dismissal for failure to state a claim. In *Pugh v. Tribune Co.,* 521 F.3d 686, 699 (7th Cir. 2008), the Court reiterated: "surviving a Rule 12(b)(6) motion requires more than labels and conclusions;" the allegations must "raise a right to relief above the speculative level." Similarly, the Court remarked in *Swanson v. Citibank, N.A.,* 614 F.3d 400, 403 (7th Cir. 2010): "It is by now well established that a plaintiff must do better than putting a few words on paper that, in the hands of an imaginative reader, *might* suggest that something has happened to her that *might* be redressed by the law." In *Atkins v. City of Chicago,* 631 F.3d 823, 831-832 (7th Cir. 2011), Judge Posner explained that *Twombly* and *Iqbal:*

> require that a complaint be dismissed if the allegations do not state a plausible claim. The Court explained in *Iqbal* that "the plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 1949. This is a little unclear because plausibility, probability, and possibility overlap....
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> But one sees more or less what the Court was driving at: the fact that the allegations undergirding a plaintiffs claim could be true is no longer enough to save it. .... [T]he complaint taken as a whole must

> establish a nonnegligible probability that the claim is valid, though it need not be so great a probability as such terms as "preponderance of the evidence" connote.... After *Twombly* and *Iqbal* a plaintiff to survive dismissal "must plead some facts that suggest a right to relief that is beyond the 'speculative level.' " *In re marchFIRST Inc.,* 589 F.3d 901, 905 (7th Cir. 2009).

V. ANALYSIS

A. The Plaintiff's Claims

The plaintiff asserts the following claims, under the Illinois Wrongful Death Act (740 ILCS 180 et seq.) and Survival Act (755 ILCS 5/27-6): (1) Strict Liability-Failure to Warn, (2) Strict Liability-Design Defect, (3) Negligence, (4) Negligent Misrepresentation and/or Fraud, (5) Breach of Express Warranty, (6) Breach of Implied Warranty of Merchantability, (7) Negligence Per Se, (8) Fraudulent Concealment, and (9) an action under the Illinois Consumer Fraud and Deceptive Practices Act. Plaintiff also requests (10) Punitive Damages and (11) Loss of Consortium. Doc. 2, Counts I-XXI, ¶¶48-268)

B. Overview of BIPI's Arguments

BIPI contends that all of the plaintiff's claims and requests for damages, viewed in the context of applicable Illinois law, fail to satisfy the *Iqbal/Twombly* pleading standard and, where applicable, the heightened pleading standard under Federal Rule of Civil Procedure 9. Additionally, BIPI contends that any claims premised on the alleged failure to adequately warn of the risk of irreversible bleeding cannot proceed because Pradaxa has always included a warning

regarding the risk of "serious and, sometimes, fatal bleeding." BIPI also raises arguments with respect to venue, the learned intermediary doctrine, and Comment K to the Restatement (Second) of Torts. Finally, BIPI raises various arguments that are specific to the plaintiff's claims for relief and for punitive damages/pre-judgment interest.

The Court addresses the relevant issues accordingly below.

C. BIPI warned about "serious and sometimes fatal bleeding"

Pradaxa has always included a statement warning consumers and physicians about the risk of "serious and sometimes fatal bleeding." According to BIPI, the plaintiff's claims cannot stand because Pradaxa carried an explicit warning about the risk of potentially fatal bleeding. This argument presumes that the inadequacies or deficiencies being alleged by the plaintiff are premised on failure to warn about the risk of serious or fatal bleeding and nothing more. The plaintiff, however, is not merely alleging that BIPI is liable because it failed to warn that Pradaxa is associated with the risk of serious and sometimes fatal bleeding. Instead, the plaintiff contends (among other things), BIPI failed to warn that, if a serious bleeding event occurs, there is no effective means for reversing the anticoagulation effects of Pradaxa. In addition, the plaintiff alleges (among other things) that BIPI failed to adequately warn about the *increased* risk of excessive or uncontrollable bleeding in patient's taking Pradaxa. Accordingly, the

fact that Pradaxa included a warning about the risk of serious or fatal bleeding does not justify dismissal of the plaintiff's claims.

D. Comment K to the Restatement (Second) of Torts § 402A

The mere fact that a product causes injury does not mean, in and of itself, that it was defective. Rather, Illinois has adopted comment k to the Restatement (Second) of Torts § 402A, which provides, in pertinent part, as follows:

> there are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified notwithstanding the unavoidable high degree of risk which they involve.

Restatement (Second) of Torts, § 402A, comment k at 353–54 (1965). Although comment k specifically mentions drugs, not all drugs fall within the purview of comment k; rather, the application of comment k must be decided on a case-by-case basis. *Glassman v. Wyeth Laboratories, Inc*., 606 N.E.2d 338, 342 (Ill. App. Ct. 1992). To come within the purview of comment k, a drug must be unavoidably unsafe, be properly prepared and have adequate warnings. *Id.*

The facts alleged in the complaint, taken as true at this point in the litigation, do not establish that Pradaxa was properly prepared or had adequate warnings. On the contrary, as discussed in the facts above, the plaintiff has alleged that Pradaxa's warnings were inadequate and that Pradaxa was

improperly designed. Further, nothing in the complaint establishes that Pradaxa is an unavoidably unsafe product. Accordingly, at this point in the litigation, the Court cannot conclude that BIPI is entitled to Comment K immunity.

E. Learned Intermediary Doctrine

Illinois law does not require a prescription drug manufacturer to provide warnings to the ultimate user or consumer. Instead, under the "learned intermediary" doctrine, prescription drug manufacturers have a duty to warn physicians of any known dangers of their drug and the physicians, in turn, have a duty to convey warnings to patients. *Kirk v. Michael Reese Hosp. and Medical Center*, 513 N.E.2d 387, 393 (Ill. 1987). If the warning provided by the manufacturer adequately explains the risks and side effects of the drug, the product is not unreasonably dangerous or defective as a matter of law. *Id*. Consequently, an adequate warning shields the manufacturer from liability if the patient suffers from those effects while taking the drug. *Id*.

If, on the other hand, a warning is inadequate and the risk is not widely-known within the medical community, the learned intermediary doctrine does not shield the manufacturer from liability. *See, e.g., Hansen v. Baxter Healthcare Corp*., 764 N.E.2d 35, 43 (Ill. 2002); *Procter v. Davis*, N.E.2d 1203, 1213 (Ill. App. Ct. 1997); Tongate v. Wyeth Labs., 580 N.E.2d 1220, 1228 (Ill. App. Ct. 1991). In the instant case, the plaintiff has alleged that BIPI failed to adequately warn physicians regarding the risks of Pradaxa and that BIPI concealed material

risk information from physicians. Accordingly, assuming the plaintiff's allegations are true, the learned intermediary doctrine does not shield BIPI from liability. *See Walton v. Bayer Corp.*, 643 F.3d 994, 1001 (a manufacturer that conceals a drug's adverse side effects from physicians is not protected under the learned intermediary doctrine).

F. Fraud Based Claims and Preemption - Fraud on the FDA

BIPI claims the plaintiff's fraud based claims are actually "fraud-on-the-FDA" claims and are therefore preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA") under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2000). In *Buckman*, the Supreme Court held that the FDCA preempts state law claims alleging that the defendant made fraudulent representations to the FDA to obtain approval for a drug or medical device and that, had the defendant not made those misrepresentations, the FDA would not have approved the drug or device and the plaintiff would not have been injured. 531 U.S. at 343–45. The plaintiff's complaint makes no mention of such a claim. Instead, the plaintiff alleges that BIPI made misrepresentations and omissions of material fact to the decedent, the decedent's physicians, the healthcare industry, and the consuming public. Accordingly, the Court is not persuaded that the plaintiff's fraud based claims are preempted based on law pertaining to fraud on the FDA.

G. Sufficiency of the Plaintiff's Allegations

1. Strict Liability – Failure to Warn or Design Defect

To prevail under a theory of strict product liability under Illinois law, a plaintiff must prove: "[1] the injury resulted from a condition of the product, [2] that the condition was unreasonably dangerous, and [3] that the condition existed at the time the product left the manufacturer's control." *Faucett v. Ingersoll–Rand Min. & Machinery Co*., 960 F.2d 653, 655 (7th Cir. 1992) (citation omitted). In a strict liability case based on a failure to warn in Illinois, the plaintiff must allege and prove that the defendant knew or should have known of the danger. *Giles v. Wyeth, Inc*., 556 F.3d 596, 600 (7th Cir. 2009) (quoting *Smith v. Eli Lilly & Co*., 137 Ill.2d 222, 148 Ill. Dec. 22, 560 N.E.2d 324, 344 (Ill.1990)).

A plaintiff may proceed under two separate theories to prove that a product is "unreasonably dangerous": (1) existence of a design or manufacturing defect or (2) failure of the manufacturer to adequately warn consumers of the product's dangers. *Lamkin v. Towe*r, 563 N.E.2d 449 (Ill. 1990). In the instant case, the plaintiff is claiming that Pradaxa was unreasonably dangerous both because of a design defect and because of a failure to adequately warn of particular dangers.

Under a design defect theory, a plaintiff can either "(1) ... introduc[e] evidence that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner (known as the "consumer expectation" test) or (2) ... introduc[e] evidence that the

product's design proximately caused his injury and the defendant fails to prove that on balance the benefits of the challenged design outweigh the risk of danger inherent in such designs." (known as the "risk-utility" test) *Lamkin*, 563 N.E.2d 449.

Under a failure to warn theory, a product that requires a warning can be considered defective at the time it left the seller if the warning is not adequate. Restatement (Second) of Torts, § 402A. If a product is considered unreasonably dangerous and that dangerousness is not generally known, then the seller "is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger." (*Id*. cmt. J.)

In the instant case, the plaintiff has alleged enough facts to state a plausible strict liability claim based on either a theory of design defect or failure to warn. For instance, the plaintiff does not merely contend that Pradaxa was in a defective condition at the time it left the manufacturer's control. Rather, the plaintiff provides specific allegations regarding Pradaxa's alleged defects, including the following: (1) Pradaxa has an *increased* risk of serious or fatal bleeding; (2) Pradaxa does not have an effective reversal agent or protocol; (3) Pradaxa is less safe than the equally efficacious prescription anticoagulant Warfarin; (4) Pradaxa places certain patient populations at an increased risk for serious or fatal bleeding; and (5) it is difficult or impossible to assess the degree and/or extent of anticoagulation in patients taking Pradaxa. Thus, the plaintiff has sufficiently

alleged the existence of an unreasonably dangerous condition under the theory of design defect. With regard failure to warn, the plaintiff contends that Pradaxa was unreasonably dangerous because it failed to warn about the defective conditions alleged in the complaint. This too states a plausible claim for relief.

With regard to a resultant injury, BIPI contends that the plaintiff's alleged injury is not sufficiently connected to Pradaxa's alleged defective conditions. For instance, BIPI states that because the plaintiff does not expressly allege the decedent suffered any injury from anticoagulation or lack of a reversal agent, the decedent's alleged injury is not sufficiently connected to the claim that Pradaxa was unreasonably dangerous because it lacked a reversal agent or protocol and/or failed to warn about the lack of a reversal agent or protocol.

The Court disagrees. The plaintiff expressly alleges that had the decedent and/or the decedent's prescribing physician known about the defects alleged in the complaint, the decedent would not have used Pradaxa. Further, the plaintiff alleges that the decedent's injury was caused by Pradaxa's allegedly defective conditions and/or BIPI's failure to warn about Pradaxa's alleged dangers. These allegations plead a right to relief that are beyond the "speculative level" and are sufficient at this stage in the litigation.

2. Fraud Based Claims

The complaint states claims for fraud, fraudulent concealment, and statutory consumer fraud (under the Illinois Consumer Fraud Act or ICFA). The

Court finds that the plaintiff's complaint states a plausible claim for relief under each of the above theories of recovery.

BIPI contends that the allegations of fraud are not sufficiently particular under Rule 9(b) and that as a result the fraud claims fail to state plausible claims for relief under Rule 8. Specifically, BIPI contends that the complaint contains no allegations demonstrating "when, where, to whom, or how" the alleged misrepresentations were made. The plaintiff responds as follows, citing to specific paragraphs within the complaint:

> [T]he Complaint pleads the "who," that is, Defendant Boehringer Ingelheim Pharmaceuticals, Inc. and its co-defendants. Compl. ¶¶ 5-8 and generally. The Complaint pleads the when and where - specifically including between October 19, 2010, id. ¶ 18, and at least April 2012, id. ¶ 40, throughout the United States. Id. ¶¶ 29(n), 35, 38, 40 (referring to U.S. labeling and prescribing information). The Complaint pleads "to whom" the representations and omissions were made, for example, to Plaintiff, id. ¶ 22, to her prescribing physician, id. ¶ 23, to emergency room doctors, surgeons, and other critical care providers, id. ¶ 24, and to primary care physicians, group practitioners, cardiologists, and practice nurses. Id. ¶ 19. Further, the Complaint pleads how the representations were made, for example, through detailing sessions, id. ¶ 19, direct to consumer advertising, id. ¶ 20, promotional materials, id. ¶ 23, the Pradaxa Medication Guide, id. ¶ 25, and the Pradaxa labeling information. Id. ¶ 29(n).

Doc. 17 p. 6.

The Court further notes that, as to the content of the alleged misrepresentations, the plaintiff alleges the Pradaxa Marketing Campaign, as well as Pradaxa's labeling and prescribing information, contained knowing misrepresentations or omissions regarding the safety and efficacy of Pradaxa,

including the following: (1) Pradaxa's efficacy and safety in relation to the prescription anticoagulant Warfarin; (2) Pradaxa's additional benefits; (3) Pradaxa's allegedly higher risk of serious bleeding; (4) the lack of an effective reversal agent or protocol in the event of a serious bleeding event; (5) the difficulty or impossibility of assessing the level or extent of anticoagulation in patients using Pradaxa; and (6) the safety risks in certain patient populations. The plaintiff also alleges intent to deceive on the part of BIPI and that both the decedent and her prescribing physician were exposed to and deceived by the allegedly deceptive information. Finally, the plaintiff alleges actual damages (damages associated with the decedent's gastrointestinal bleed and death) caused by the alleged deception (the plaintiff alleges that had the decedent or her prescribing physician not been deceived she would not have taken Pradaxa).

Considering the above allegations, the Court finds that the plaintiff has pled, with sufficient particularity, claims for fraud, fraudulent concealment, and statutory consumer fraud.

3. Negligence

In Illinois, product liability cases asserting negligence fall under the standard of common law negligence. *Calles v. Scripto–Tokai Corp.*, 864 N.E.2d 249, 263 (Ill. 2007). The Plaintiff in this case must therefore allege "the existence of a duty of care owed by the defendant, a breach of that duty, an injury that was proximately caused by that breach, and damages." *Id.*

BIPI argues that the plaintiff's negligence claim is premised on failure to warn and fails to state a claim upon which relief may be granted because the plaintiff attempts to place a duty on BIPI to directly warn the plaintiff and the "general public," when its only duty was to warn the *prescribing* physician. The Court agrees that under the learned intermediary doctrine a prescription drug manufacturer does not have a duty to directly warn consumers about a drug's adverse risks. Thus, to the extent that the plaintiff's negligence claim asserts BIPI owed the decedent or the general public a duty to *warn*, it must fail. No such duty exists (this is so regardless of whether the learned intermediary doctrine will ultimately shield BIPI from liability for claims premised on a failure to warn in the instant case).

The learned intermediary doctrine, however, does not establish that BIPI, as a prescription drug manufacturer, owes no duty to users of Pradaxa. Under Illinois law, a manufacturer has a duty of due care to design and manufacture a product that will be reasonably safe for its intended use. *See e.g., Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 270 (Ill. 2007) (manufacturer's nondelegable duty to design reasonably safe products); *Salerno v. Innovative Surveilance Technology, Inc.*, 932 N.E.2d 101, 111 (Ill. App. Ct. 2010) (manufacturer has a nondelegable duty to design reasonably safe products); *Cornstubble v. Ford Motor Co.*, 532 N.E.2d 884, 886 (Ill. App. Ct. 1988) (duty to design and manufacture a product that is reasonably safe for its intended use).

Although, for claims premised on failure to warn, the learned intermediary doctrine limits the class of persons to whom the warning is required to be given, it does not abolish a prescription drug manufacturer's duty to design and manufacture a reasonably safe product. In other words, a prescription drug manufacturer owes a duty to design and manufacture a product that is reasonably safe for its intended use. This duty can be breached in a number of ways, some of which have nothing to do with failure to warn. To the extent that failure to warn is in issue, the manufacturer only has a duty to warn prescribing physicians

In the instant case, the plaintiff has adequately alleged the existence of a duty. *See* Doc. 2 ¶ 90 (alleging BIPI owed "a duty to the general public and specifically to [the decedent] to exercise reasonable care in the design, study, development, manufacture, promotion, sale, labeling, marketing and distribution of Pradaxa"). The plaintiff has also asserted that BIPI violated this duty. *See e.g. Id*. at ¶ 91 (BIPI failed to "exercise reasonable care in the developing, testing, designing and manufacturing of Pradaxa"); *Id*. at ¶ 106(a) (alleging BIPI failed to "design and/or manufacture a product that could be used safely due to the lack of a known reversal agent"); *Id.* at ¶ 23 (alleging BIPI failed to adequately warn decedent's prescribing physician about the risks associated with Pradaxa) (incorporated by reference into the plaintiff's negligence claims).

For the reasons stated above, The Court concludes that the plaintiff has sufficiently stated a claim for common law negligence.

4. Negligence Per Se

The plaintiff asserts claims for negligence per se. These claims reference alleged violations of the Food, Drug and Cosmetic Act (FDCA). BIPI contends that these claims are based on the FDCA and are barred because there is no private cause of action under the FDCA. The plaintiff responds arguing that the plaintiff's per se negligence claims are based on Illinois common law and that reference to the FDCA is merely the basis for the applicable standard of care.

Under Illinois law, "if a statute defines what is due care in some activity, the violation of the statute either conclusively or (in Illinois) presumptively establishes that the violator failed to exercise due care." *Cuyler v. United States,* 362 F.3d 949, 952 (7th Cir. 2004). The statutory definition of due care, however, only comes into play if the defendant owes a duty of care to the injured party – in this case the decedent. *Id*. In the instant case, the plaintiff has alleged that, under Illinois common law, BIPI owed a duty of care to the decedent and that the FDCA provides the definition for the standard of care owed to the decedent. Accordingly, the fact that there is no private right of action under the FDCA does not warrant dismissal of the plaintiff's negligence per se claims. *See e.g., Id.*; *Wigod v. Wells Fargo Bank, N.A.,* 673 F.3d 547, 582 (7th Cir. 2012).

Further, for reasons already discussed, the Court also finds that the plaintiff has asserted facts sufficient to support a plausible claim for relief under the theory of negligence per se.

5. Breach of Express Warranty

With regard to the plaintiff's breach of express warranty claim, BIPI contends the plaintiff has failed to plead facts that could be construed as an express warranty or as reliance on an express warranty. The Court notes the following allegations in the plaintiff's complaint:

Existence of a Warranty

- "Defendant[] expressly warranted that Pradaxa was a safe and effective prescription blood thinner," Doc. 2 ¶ 134, 141;
- Defendant overstated the efficacy of Pradaxa; id. ¶ 21 (incorporated into Count IX and Count X in ¶ 132, 139);
- Defendant disseminated to the decedent and her physicians inaccurate, misleading, and false information, id. at ¶ 94(a), 106(a) (incorporated into Count IX and Count X in ¶ 132, 139); and
- Pradaxa was as safe or safer, and as effective or more effective, than other anticoagulation alternatives. *Id*. ¶ 113, 124 (incorporated into Count IX and Count X in ¶ 132, 139).

Reliance

- The decedent and/or her physicians justifiably relied on BIPI's representations *id*. ¶ 118, 129 (incorporated into Count IX and Count X in ¶ 132, 139)

- Had the decedent and her physicians known of the risks of Pradaxa and the lack of additional benefits, the decedent would not have ingested Pradaxa. *id*. at ¶ 46 (incorporated into Count IX and Count X in ¶ 132, 139).

In light of these allegations, the Court finds that the plaintiff has sufficiently alleged a claim for breach of express warranty.

6. Breach of Implied Warranty of Merchantability

"To succeed on a breach of implied warranty of merchantability claim "a plaintiff must establish (1) a sale of goods, (2) that the seller of the goods is a merchant with respect to those goods, and (3) that the goods were not of merchantable quality." *Maldonado v. Creative Woodworking Concepts, Inc*., 796 N.E.2d 662, 666 (Ill. App. Ct. 2003). A product that is not of merchantable quality is one that is unfit for the ordinary purposes for which the goods are used. *Maldonado*, 796 N.E.2d at 666.

In addition to arguing that the breach of warranty claims are barred by the learned intermediary doctrine and comment K to the Restatement (Second) of Torts 402A (issues the Court has already addressed), BIPI contends that "there can be no claim" that Pradaxa "did not function in an otherwise merchantable manner." The Court disagrees, the plaintiff has alleged numerous deficiencies related to Pradaxa. In addition, the plaintiff has alleged that the decedent was hospitalized due to excessive bleeding as a result of ingesting Pradaxa. These

allegations go to the issue of merchantability and are sufficient for surviving BIPI's motion to dismiss.

H. Punitive Damages and Prejudgment Interest

BIPI asks the Court to strike the plaintiffs requests for punitive damages and prejudgment interest. The Court finds that a more fully developed record is necessary for determining whether these claims are appropriate in the instant case and denies the request to strike as premature.

I. Venue

BIPI seeks dismissal based on improper venue. Where, as here, jurisdiction is based solely on diversity, venue is determined in accordance with the requirements of 28 U.S.C. § 1391(a). Pursuant to this provision, such an action may be brought:

> only in (1) a judicial district where any defendant resides, if all defendants reside in the same State, (2) a judicial district in which a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated, or (3) a judicial district in which any defendant is subject to personal jurisdiction at the time the action is commenced, if there is no district in which the action may otherwise be brought.

Id. In the instant case, the plaintiff has made the following allegations: (1) the events giving rise to the plaintiff's claims occurred in the Southern District of Illinois (doc. 2 ¶ 12); (2) BIPI resides in this judicial district, *id*. ¶ 11; (3) at all relevant times the decedent was a resident and citizen of Jerseyville, Illinois in Madison County, id. ¶ 1; and (4) shortly after being prescribed Pradaxa, the

decedent suffered a severe gastrointestinal bleed, her excessive bleeding was worsened by Pradaxa, and her bleeding caused her to be hospitalized at Alton Memorial Hospital, *id*. ¶ 43.

Assuming that the above allegations are true, venue is proper and BIPI is not entitled to dismissal based on improper venue.

VI. CONCLUSION

For the reasons set forth above, BIPI's Motion to Dismiss is **DENIED**.

IT IS SO ORDERED.

David R. Herndon
2012.07.24
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Chief Judge **Date: July 24, 2012**
United States District Court