IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

HUNTINGTON DIVISION

CLAUDE R. KNIGHT and
CLAUDIA STEVENS, individually
and as Personal Representatives of
the Estate of Betty Erelene Knight, deceased,

Plaintiffs,

v. CIVIL ACTION NO. 3:15-6424

BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC.

Defendant.

MEMORANDUM OPINION AND ORDER

Pending before the Court are a litany of motions, including Defendant's Motion for Summary Judgment (ECF No. 42) and Plaintiffs' Motion for Partial Summary Judgment (ECF No. 44). Importantly, four of Defendant's other still-pending motions are relevant to its summary judgment motion: Motion to Exclude Case-Specific Testimony of Dr. Hazem Ashhab (ECF No. 45) ("Motion to Exclude Dr. Ashhab"); Motion in Limine No. 3 to Exclude Evidence, Testimony, or Argument Related to Foreign Regulatory Actions, Foreign Labeling Materials and Company Core Data Sheet (ECF No. 65) ("Foreign Label Motion"); Motion in Limine No. 4 to Exclude Evidence and Argument Regarding Lack of a Reversal Agent (ECF No. 66) ("Reversal Agent Motion"); Motion in Limine No. 6 to Exclude Evidence and Argument Regarding Plasma Concentration Levels (ECF No. 68) ("Plasma Levels Motion"). In addition to fully briefing the motions, the parties provided oral argument before the Court at the Pretrial Motions Hearing on May 15, 2017. As explained below, the Court **GRANTS, IN PART, AND DENIES, IN PART**

Defendant's Motion for Summary Judgment (ECF No. 42), **DENIES** Plaintiffs' Motion for Partial Summary Judgment, **DENIES** Defendant's Motion to Exclude Dr. Ashhab (ECF No. 45), **DENIES** Defendant's Foreign Label Motion (ECF No. 65), **DENIES** Defendant's Reversal Agent Motion (ECF No. 66), and **DENIES** Defendant's Plasma Levels Motion (ECF No. 68).

I. BACKGROUND

This case is one in a series of product liability suits brought around the country, in which plaintiffs have claimed that they were harmed due to allegedly defective aspects of Pradaxa, a drug created and sold by Defendant Boehringer Ingelheim Pharamaceuticals, Inc. ("BI"). See generally Chambers v. Boehringer Ingelheim Pharmaceuticals, Inc., No. 4:15-CV-00068 (CDL), 2018 WL 849081 (M.D. Ga. Jan. 2, 2018); Warren v. Boehringer Ingleheim Pharmaceuticals Inc., No. 1:16-cv-01326-SEB-DML, 2017 WL 3970666 (S.D. Ind. Sept. 8, 2017). In this variation of the nation-wide cases, Ms. Betty Knight had been taking Pradaxa for roughly 18 months before she suffered a serious gastrointestinal bleed in May 2013. *Ex. 1 to Pls.' Resp. to Summ. J.*, ECF No. 51-1, at 2-3. Although doctors eventually stopped the bleed, Ms. Knight remained largely debilitated, being moved in and out of in-patient care facilities, hospitals, and her home. Id. A few months later, in September 2013, Ms. Knight passed away at the age of 84. Id. at 4; *Ex. 3 to Def.'s* Mot. for Summ. J., ECF No 41-3, at 2.

A. Ms. Knight's Medical Condition and Events Leading to her Passing

Among other conditions[1], Ms. Betty Knight suffered from atrial fibrillation ("A-Fib"), a condition in which the heart beats irregularly. *Ex. 1 to Def.'s* Mot. for Summ. J., ECF No. 42-1, at 3-4; *Ex. 3 to Def.'s Mot. for Summ. J.*, at 2. This irregular heart beat can cause a pooling of blood

[1] Ms. Knight also had other health conditions, including coronary artery disease, peripheral vascular disease, diabetes, and renal disease. *Ex. 1 to Def.'s Mot. for Summ. J.*, at 4.

in areas of the heart, and can lead to the development of blood clots. Ex. *1 to Def.'s Mot. for Summ.* J., at 3-4. Significantly, if these clots break away and travel to the brain, the suffering patient can have a stroke. Id.

Ms. Knight's A-Fib, in addition to her being over 75 years-old, increased her stroke risk. *Ex. 1 to Def.'s Mot. for Summ. J.*, at 4. In fact, largely because of these two factors, Ms. Knight's primary care physician, Dr. Dawn MacFarland, characterized Ms. Knight has having a high risk of stroke. Id.

As early as 2005, doctors had prescribed medicine to Ms. Knight in order to lessen her atrial fibrillation-related stroke risk. *Ex. 1 to Pls.' Resp. to Summ. J.*, at 2. The first drug Ms. Knight received was warfarin, which is marketed under the brand name Coumadin. Like Pradaxa, warfarin works as an anticoagulant that helps to prevent the development of blood clots, thereby reducing the risk of stroke. *Ex. 4 to Pls.'s Resp. to Summ. J.*, ECF No. 51-4, at 22-23. And as with the use of any anticoagulant drug, warfarin increases the risk of a patient experiencing bleeding. Id. at 20.

In order to address and mitigate the bleed risk associated with warfarin use, patients must submit to stringent dietary restrictions and a regular and frequent monitoring regime. Id. at 22-24; *Ex. 8 to Pls.' Resp. to Summ. J.*, ECF No. 51-8, at 6-8; *Ex. 1 to Def.'s Mot. to Summ. J.*, at 5-6; Ex. *9 to Pls.' Resp. to Summ. J.*, ECF No. 51-9, at 3. Warfarin has a narrow therapeutic range, which is a range of anticoagulant effect that decreases the risk of stroke without unnecessarily increasing the risk of a bleed. *Ex 4 to Pls.' Resp. to Summ. J.*, at 22-23. Based upon the measurement levels reflected during the monitoring tests, doctors adjust a patient's warfarin dose in an effort to keep the patient in the therapeutic range. Id.

During her time on warfarin, Ms. Knight regularly submitted to this monitoring. Despite the inconvenience it posed to Ms. Knight, the regular testing was critical to her warfarin treatment.

According to her doctors, they had a difficult time managing Ms. Knight's warfarin levels. Ex. 1 *to Def.'s Mot. for Summ. J.*, at 6. In fact, Ms. Knight's warfarin levels regularly fell outside of the therapeutic range. Id. Indeed, even while on warfarin, Ms. Knight's monitoring reflected that at times she was over-anticoagulated. Id. at 7. Despite this intermittent over-anticoagulation on warfarin, Ms. Knight did not experience a major bleed while on the medicine.

With the numerous restrictions of warfarin, Ms. Knight and her family were interested in getting her on a different anticoagulant that would intrude less upon Ms. Knight's everyday activities. *Ex. 1 to Def.'s Mot. for Summ. J.*, at 7-8. And, prompted by a commercial they saw which touted the benefits of Pradaxa, Ms. Knight and her children made an appointment to speak with Dr. MacFarland about switching Ms. Knight to Pradaxa. Id.; *Ex. 9 to Pls.' Resp. to Summ*. J., at 2; *Ex. 1 to Pls.' Resp. to Summ. J.*, at 2.

Ms. Knight and her children visited Dr. MacFarland's office on October 17, 2011, at which point Ms. Knight first received a prescription for Pradaxa. *Ex. 1 to Def.'s Mot.* for Summ. J., at 12-13; *Ex. 1 to Pls.' Resp. to Summ. J.*, at 2. Freed from the warfarin related constraints, Ms. Knight enjoyed not having to regularly submit to the monitoring and testing of her anticoagulant levels. *Ex. 9 to Pls.' Resp. to Summ. J.*, at 9. Instead of the frequent dose adjustment involved with warfarin, Dr. MacFarland's office prescribed a set dose for Ms. Knight's Pradaxa, 75 mg B.I.D. *Ex. 1 to Pls.' Resp. to Summ. J.*, at 2. For sales in the United States, Pradaxa's package insert, often referred to as the "label," recommended that doctors prescribe either a dose of 75 mg or 150 mg, dependent upon the patient's renal function. Id.; *Ex. 2 to Pls.' Resp. to Summ. J.*, ECF No. 51-2, at 2. Based upon Ms. Knight's severe kidney impairment, the Pradaxa label recommended the 75 mg dose, twice a day. Id. Dr. MacFarland's prescription followed the label's dosing recommendation. Id.; *Ex. 8 to Pls.' Resp. to Summ. J.*, at 8-9. At the time of her initial prescription,

Ms. Knight was 82 years old, and took two P-gp inhibitor drugs, as well as Iburprofen three times a day. *Ex. 1 to Pls.' Resp. to Summ. J.*, at 2.

In April 2013, Ms. Knight went to the hospital after suffering from a heart attack. Ex. 3 to *Def.'s Mot. for Summ. J.*, at 3. At the hospital, Ms. Knight underwent a left heart catheterization, with stint placement. Id. After the procedure, doctors continued to give Ms. Knight her Pradaxa, and required her to take two other drugs: Plavix and aspirin. Id.; *Ex. 1 to Pls.' Resp. to Summ. J.*, at 2. Plavix is an anti-platelet drug that affects the blood's clotting, and was prescribed to Ms. Knight to address her cardiac risk after the placement of two stints. Id. So too, taking aspirin also helps to prevent heart attacks. Doctors refer to the prescription of Pradaxa, Plavix, and aspirin together as "triple therapy." *Ex. 3 to Def.'s Mot. for Summ. J.*, at 2; *Ex. 4 to Def.'s Mot. for Summ.* J., ECF No. 42-4, 8-10. Like Pradaxa, both Plavix and aspirin increase the risk of bleeding. Ex. 3 *to Def.'s Mot. for Summ.* J., at 2; *Ex. 4 to Def.'s Mot. for Summ. J.*, at 9; *Ex. 5 to Def.'s Mot. for* Summ. J., ECF No 42-5, at 5; *Ex. 7 to Pls.' Resp. to Summ. J.*, ECF No. 51-7, at 2.

On May 20, 2013, almost a month after she had started the triple therapy, Ms. Knight reported to her doctors that she was experiencing symptoms indicative of gastrointestinal bleeding. *Ex. 4 to Def.'s Mot. for Summ. J.*, at 10-11; *Ex. 1 to Pls.' Resp. to Summ. J.*, at 3. According to her medical records, Ms. Knight had been experiencing those symptoms for roughly a week by the time she visited her doctor. *Ex. 1 to Pls.' Resp. to Summ. J.*, at 3. The bleed symptoms had continued to worsen over that time, and Ms. Knight was admitted to the hospital. Id.

Dr. Ahmed Abdelgaber, the doctor treating Ms. Knight at the hospital, directed that she not receive her Pradaxa, Plavix, or aspirin, due to the active, serious bleed. Id.; *Ex. 3 to Def.'s Mot. for* Summ. J., at 4. The next day, May 21, 2013, despite having not received the "triple therapy" medicines for over twenty-four hours, a coagulation test performed on Ms. Knight indicated that

she was over-anticoagulated. Id. Ms. Knight's aPTT, a test that measures the level of anticoagulation, registered 47 seconds, an elevated score that reflected over-anticoagulation. Id.

Dr. Charles Huh, a gastroenterologist, performed a endoscopy and a colonoscopy. Id.; Ex. *3 to Def.'s Mot. for Summ. J.*, at 4. Dr. Huh found an active bleed in Ms. Knight's colon; he believed the bleed was due to an arteriovenous malformation. Dr. Huh stopped the active bleed by applying two endoscopic clips. Four days after her procedures, Ms. Knight was released from in-patient care, and transferred to the skilled nursing unit of St. Mary's Medical Center. Id. At some point shortly after her procedure, Ms. Knight resumed taking her Pradaxa. Id.

Despite stopping the bleed, and resuming her Pradaxa, Ms. Knight's health still struggled. According to doctors who saw her in June and July of 2013, she was "not bouncing back" and she had "been weak since [her admission to the hospital]." Id. Additionally, during an appointment with a cardiologist that summer, and while still taking her Pradaxa, Ms. Knight had an another aPTT test showing that she was over-anticoagulated. Id. This time, her aPTT resulted in 67 seconds, indicating even greater over-anticoagulation. Id.

Throughout that summer, Ms. Knight was admitted to the hospital various times, and generally did not demonstrate any improvement. Id. at 3-4. In one of her last admissions to the hospital, from August 17, 2013 until August 22, 2013, Ms. Knight received treatment at St. Mary's Medical Center after suffering a heart attack. Id. at 4; *Ex. 3 to Def.'s Mot. for Summ. J.*, at 5. Finally, just a few days after being released, on September 1, 2013, she was admitted again to St. Mary's Medical Center, but for the last time. Id. With an aPTT of 54 seconds at the time of her final hospitalization, Ms. Knight continued to demonstrate over-anticoagulation. Id. However, at no point during the multiple hospitalizations after May 2013 did Ms. Knight suffer another major

bleed. The next day, on September 2, 2013, Ms. Knight passed away. Id.; *Ex. 3 to Def.'s Mot. for* Summ. J., at 5.

B. Pradaxa and its Label

Approved by the FDA in October of 2010, Pradaxa belongs to a relatively new class of drugs developed to provide an alternative to warfarin for stoke prevention in patients with atrial fibrillation. *Ex. 4 to Pls.' Resp to Summ. J.*, at 24. In seeking FDA approval of Pradaxa, BI conducted a clinical trial called RE-LY, in which it tested dosages of 110 mg and 150 mg. Id. at 26. During the RE-LY trial, which involved thousands of participants, researchers measured the blood plasma concentration of dabigatran, the substance created by taking Pradaxa. Id. The concentrations varied widely. For people taking 150 mg of Pradaxa, their tough level of dabigatran—the level right before patients were supposed to take their next dose—ranged from 1.4 ng/ml to 809 ng/ml. Id. at 26. Even the 10^{th} and 90^{th} percentiles of Pradaxa plasma concentration demonstrated wide variability, going from 39.8 ng/ml to 215 ng/mL, respectively. Id. at 27. However, BI found that the potential "sweet spot" for diagatran plasma concentrations—the level at which the potential benefit of stroke prevention outweighed, or at least matched, the increased risk of bleeding—was between approximately 50 ng/ml and 150 ng/ml. Id. at 29-30. Although at least twenty percent of trial patients fell outside that range, the risks associated with falling outside that range were potentially dire. Id. at 26-36.

BI's RE-LY trial showed that in patients with plasma concentrations of roughly 210 ng/mL or greater, the risk of stoke did not really change, but the risk of experiencing a major bleed doubled. Id. at 31. In a different, later trial, BI again confirmed this doubling of the major bleed risk when patients' plasma concentration met or exceeded a certain level. Id. Largely consistent with the earlier findings, in the later trial BI found that at 215 ng/ml patients' risk of a major bleed

doubled. Id. Even BI's internal emails between its medical staff demonstrate the understanding that the blood plasma concentration of diagatran should not exceed roughly 200 ng/mL. In one email, the principle investigator for the RE-LY study told his colleagues that

> the obvious implication of these data [is] that they point to a trough plasma concentration range for optimization of efficacy and safety in a range from 40-200 ng/ml. We need to say this more direct[ly]. Of course there is some uncertainty but the data are fairly clear. **There is very good reason to never go above 200 ng/ml**.

Id. at 33 (emphasis original to report).

Despite the observation of BI and its employees that certain blood plasma concentrations of Pradaxa increased the risk of a major bleed without contributing any additional stroke prevention benefit, BI did not place this information in either Pradaxa's label or the Medication Guide that went to patients. *Ex. 4 to Pls.' Resp. to Summ. J.*, at 16-17; see generally *Ex. 2 to Pls.'* Resp. to Summ. J. Furthermore, BI did not include in those publications that the potentially dangerous concentrations appeared in patients who took the medication as recommended. Id.

However, this was not the only pertinent information lacking from Pradaxa's label and Medication Guide, according to Plaintiffs. Although it apparently had information demonstrating that certain patients, who both suffer from severe renal impairment and take medications called P-gp inhibitors, should not take Pradaxa, BI did not include that information in the original label or Medication Guide. *Ex. 3 to Pls.' Resp. to Summ. J.*, ECF No. 51-3, at 7-11; see generally Ex. 2 to *Pls.' Resp. to Summ. J.* Later, BI did add information regarding the risk associated with those patients who both have renal impairment and take P-gp inhibitors. But BI did not take any additional steps to notify doctors or patients of this change. Instead, it merely changed the text of the label without bringing further attention to the alteration.

Indeed, when Ms. Knight first received her prescription for Pradaxa, the label did not contain a specific warning about either the doubling risk at a certain level of plasma concentration or the risk associated with concomitant use of P-gp inhibitors. *Ex. 3 to Pls.' Resp.* to Summ. J., at 7-11; see generally *Ex. 2 to Pls.' Resp. to Summ. J.* The amendment adding this warning came shortly after Ms. Knight was first prescribed Pradaxa. In that amendment, BI included at least some information regarding the increased bleed risk associated with simultaneous use of P-gp inhibitors in patients with renal impairment. Id. But at no point, other than having a general warning regarding a risk of bleeding, did BI detail the possibility of dangerous concentrations of Pradaxa that doubled the bleed risk without adding any meaningful stroke prevention. *Ex. 1 to Pls.' Resp.* to Summ. J., at 4-5.

In other markets, however, BI inserted this information into the package warnings for Pradaxa. For example, the Pradaxa label for the medication sold in Europe included warnings both about the increased risk of bleeding in patients whose plasma concentration exceed 200 ng/ml, and about the increased bleed risk in older individuals with renal impairment who are also on a P-gp inhibitor. *Ex. 4 to Pls.' Resp. to Summ*. J., 49-52; *Ex. 14 to Pls.' Resp. to Summ. J.*, ECF No. 51-14, at 4-6. Consistent with this warning, BI recommended that European physicians should test the dabigatran exposure in patients with a high bleed risk. Id. BI also provided the same warning and instruction to doctors and patients in Canada. Id. at 49. In fact, in the U.K. label, BI went as far as instructing prescribing doctors and patients that "the exposure [ ] to dabigatran [(Pradaxa)] was approximately 6 times higher [in patients with severe renal insufficiency, like Ms. Knight,] . . . than that observed in [patients] without renal insufficiency." *Ex. 14 to Pls.' Resp. to Summ. J.*, at 25.

Not only did BI not alert patients and doctors in the United States about some of the quantified, increased risks of bleeding in patients with certain characteristics, but it also appears that BI did not notify the FDA of at least some of the relevant risk information. Seemingly, despite having information regarding the doubled risk associated with Pradaxa concentrations of over roughly 200 ng/mL, BI never informed the FDA of this "cut-off value." *Ex. 33 to Pls.' Resp. to* Summ. J., ECF No. 51-33, at 103.

C. Development of Praxbind, the Antidote to Pradaxa

When Pradaxa first hit the market, there was no way to reverse its effects if a patient was suffering a bleed due to over-anticoagulation. For those suffering from such a bleed, treating medical teams could only attempt to manage the bleed. *Ex. 26 to Pls.' Resp. to Summ. J.*, ECF No. 51-26. BI's own medical developers noted that there was "an unmet medical need for reversal agents . . . to reverse the anticoagulant effects of [drugs like Pradaxa]." *Ex. 25 to Pls.' Resp. to* Summ. J., ECF No. 51-25, at 7-8. However, by 2015, BI had discovered, produced, and received approval for an antidote for Pradaxa called Praxbind. *See generally Ex. 23 to Pls.' Resp. to Summ.* J., ECF No. 51-23.

In 2002, during the early stages of Pradaxa's formulation, BI first discovered the antibody that would catalyze the development of Praxbind. *Ex. 24 to Pls.' Resp. to Summ. J.*, ECF No. 51-24, at 2-3; *Ex. 19 to Pls.' Resp. to Summ. J.*, ECF No. 51-19, at 2. However, it was not until 2008 that the BI team realized that this antibody might provide a base from which to build an antidote to the anticoagulant effects of Pradaxa. *Ex. 19 to Pls.' Resp. to Summ. J.*, at 1. After that antibody was "humanized," BI doctors produced the antidote for testing and trials. *Ex. B Def.'s Reply in Supp. of Def.'s Reversal Agent Motion*, ECF No. 98-2, at 8-9. Reflecting its urgency to get Praxbind on the market, BI requested accelerated approval from the FDA. *Ex. 26 to Pls.' Resp. to*

Summ. J., at 1. Citing the need of Praxbind, the FDA granted the accelerated approval. Ex. 23 to *Pls.' Resp. to Summ. J.*, at 1. In all, the Praxbind development process and FDA approval took six years, a relatively short time for medications. *Ex. B Def.'s Reply in Supp. of Def.'s Reversal Agent* Motion, at 6-7.

Studies demonstrated that Praxbind quickly and effectively reversed the effects of Pradaxa. This made it an antidote in cases where patients' anticoagulation resulted in a dangerous bleed. *Ex. 27 to Pls.' Resp. to Summ. J.*, ECF No. 51-27, at 6-7. The drug works by binding to dabigatran, the substance produced by Pradaxa that leads to anticoagulation, thus making dabigatran unavailable for use in the body. *Ex. 26 to Pls.' Resp. to Summ. J.*, at 1. Based upon these results, BI presented Praxbind as an "enhance[ment to] the safety profile of [Pradaxa]," which would increase the value of Pradaxa. *Ex. 25 to Pls.' Resp. to Summ. J.*, at 8-9; *see Ex. 31 to Pls.' Resp. to* Summ. J., ECF No. 51-31.

D. Plaintiffs' Claims

Upon these facts, Plaintiffs advance a list of claims, all generally alleging that BI is liable for Ms. Knight's death due to the defective nature of, and inadequate warnings for, Pradaxa. Plaintiff's first claim, Strict Products Liability (Count I), encompasses two theories: (1) that Pradaxa was defectively designed, and (2) that BI failed to adequately warn Ms. Knight about the dangers of taking Pradaxa. See Pls. Resp. to Summ. J., ECF No. 51, at 2-3. Specifically, Plaintiffs claim that Pradaxa was defectively designed at the time that Ms. Knight took it because there was no way to reverse Pradaxa's anticoagulant effect.

Regarding the warnings, Plaintiffs claim that BI failed to provide sufficiently specific information, and that the Pradaxa label and Medication Guide lacked important information, which rendered them misleading and inadequate. Id. at 2. Plaintiffs' warnings claims break down roughly

into three independent components. First, according to Plaintiffs, BI failed to include information regarding the higher risk of major bleeding events for patients who both suffer from severe renal impairment and take P-gp inhibitors. Id. at 3. Once BI did change the label to include a portion of the warning information for those with renal impairment who take P-gp inhibitors, Plaintiffs claim BI failed to properly bring that change to the attention of patients or prescribing doctors through a "Dear Doctor Letter." Id. Second, BI never warned patients or doctors that there was a concentration level of Pradaxa which patients should not exceed due to the exponential increase in bleed risk. And, Plaintiffs contend that BI should have, but did not, instruct physicians to take measurements of the Pradaxa concentration to avoid a heightened bleed risk. Coupled with that recommendation to monitor, Plaintiffs assert that BI should have identified a test for doctors to accurately measure Pradaxa concentration levels. Third and finally, Plaintiffs contend that BI knew, but failed to make clear, the specific multipliers of risk increase associated with patient characteristics such as age, concomitant medications, and renal impairment. All of which, had they been in place, would have prevented Ms. Knight from suffering the alleged fatal bleed.

Additionally, Plaintiffs assert a variety of common law and statutory claims including: negligence (Count II), negligent misrepresentation/fraud (Count III), breach of express warranty (Count IV), breach of implied warranty (Count V), negligence per se (Count VI), fraudulent concealment (Count VIII), and a claim for punitive damages (Count IX). Generally, Plaintiffs supports these claims based upon the same arguments and evidence as their defective design and failure to claims.

II. STANDARD OF REVIEW

A. Summary Judgment Standard

To obtain summary judgment, the moving party must show that no genuine issue as to any material fact remains and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). "Material facts" are those that might affect the outcome of a case, and a "genuine issue" exists when a reasonable jury could find for the nonmoving party upon the evidence presented. *The News & Observer Publ'g Co. v. Raleigh*-Durham Airport Auth., 597 F.3d 570, 576 (4th Cir. 2010) (citing Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). In considering a motion for summary judgment, the Court will not "weigh the evidence and determine the truth of the matter[.]" Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). So too, it is not the province of the Court to make determinations of credibility. Gray v. Spillman, 925 F.2d 90, 95 (4th Cir. 1991). Instead, the Court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587-88 (1986). Any inference, however, "must fall within the range of reasonable probability and not be so tenuous as to amount to speculation or conjecture." JKC Holding Co. v. Wash. Sports Ventures, Inc., 264 F.3d 459, 465 (4th Cir. 2001) (citation omitted).

Although the Court views all underlying facts and inferences in the light most favorable to the nonmoving party, in order to survive summary judgment, the nonmoving party must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor[.]" Anderson, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and, after adequate time for discovery, does not make a showing sufficient to establish that element. See Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). The nonmoving party must satisfy this burden of proof by offering more

than a mere "scintilla of evidence" in support of his or her position. Anderson, 477 U.S. at 252. "Mere speculation by the non-movant cannot create a genuine issue of material fact" to avoid summary judgment. JKC Holding Co., 264 F.3d at 465.

B. Daubert Standard

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert witness testimony. A qualified expert's testimony is admissible if it "rests on a reliable foundation and is relevant[.]" Daubert v. Merrell Dow Pharm. Inc., 509 U.S. 579, 597 (1993). There is no mechanistic test for determining if an expert's proffered relevant testimony also is reliable. Rather, "'the test of reliability is flexible' and 'the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination.'" United States v. Wilson, 484 F.3d 267, 274 (4th Cir. 2007) (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 141-42 (1999) (italics original in Kumho)).

To fulfill its gatekeeping responsibility, the court must determine whether: (1) "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;" (2) "the testimony is based on sufficient facts or data;" (3) "the testimony is the product of reliable principles and methods;" and (4) "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(a)–(d). "This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Daubert, 509 U.S. at 592-93.

In considering reliability, the Court must ensure that the expert opinions are "'based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods.'" Nease v. Ford Motor Co.,

848 F.3d 219, 229 (4th Cir. 2017) (quoting Oglesby v. Gen. Motors Corp., 190 F.3d 244, 250 (4th Cir. 1999) (italics original)). "[E]xpert witnesses have the potential to be both powerful and quite misleading[.]" PBM Prods., LLC v. Mead Johnson & Co., 639 F.3d 111, 123 (4th Cir. 2011) (internal quotation marks and citations omitted). Therefore, the Court's gatekeeping role with respect to experts is critical. When experts formulate opinions from existing data, "nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit[—translation: "he himself said it"—]of the expert." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). When an expert's opinion is based upon mere ispe dixit, "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." Id. (citation omitted).

III. DISCUSSION

Because Defendant's four preliminary motions affect the consideration of its Motion for Summary Judgment, the Court will first address those preliminary motions. After reaching a conclusion as to the Motion to Exclude Dr. Ashhab, the Plasma Levels Motion, the Foreign Label Motion, and the Reversal Agent Motion, the Court will analyze Defendant's Motion for Summary Judgment and Plaintiffs' Motion for Partial Summary Judgment.

A. Preliminary Motions

a. Motion to Exclude Dr. Ashhab

In probably the most consequential preliminary motion, Defendant moves this Court to exclude the testimony and opinions of Plaintiffs' only case-specific expert, Dr. Hazem Ashhab. Defendant contends that Dr. Ashhab's opinions are both speculative and unsupported. *Def.'s Mem.* in Supp. of Mot. to Exclude Dr. Ashhab, ECF No. 46, at 1. As such, Defendant argues that his

opinions fail to meet the reliability requirement announced in Daubert v. Merrell Dow Pharm., 509 U.S. 579 (1993). Id. at 5-16.

Dr. Ashhab is a board-certified gastroenterologist with a lengthy history of experience. Ex. *17 to Pls.' Resp. to Def. Mot. to Exclude Dr. Ashhab*, ECF No. 53-18, at 1. His report summarizes Ms. Knight's course of treatment following diagnoses of atrial fibrillation and other significant medical conditions. See generally id. In preparation for his report, Dr. Ashhab reviewed treatment records and deposition transcripts from the principal physicians who cared for Ms. Knight during the relevant period. Id. at 1. In his report, he offers four main opinions, summarized below:

1) Pradaxa caused or contributed to Ms. Knight's gastrointestinal bleed in May 2013;
2) she was over-anticoagulated with Pradaxa at the time of her bleed but Praxbind would have lessened or stopped the bleed;
3) she continued to be over-anticoagulated up to the time of her death, at least in part due to Pradaxa, as evidenced by her elevated aPTT levels, and Defendant failed to inform and instruct her physicians how to monitor Pradaxa concentration, in order to reduce the Pradaxa dose or switch to another anticoagulant; and
4) the May 2013 bleed contributed to her death.

Id. 2-5; *Def.'s Mem. in* Supp. of Mot. to Exclude Dr. Ashhab, at 4 n.1.

Assailing Dr. Ashhab's opinion that Ms. Knight was over-anticoagulated as a result of Pradaxa when she was hospitalized in May 2013, Defendant contends Dr. Ashhab's deposition testimony reveals inconsistencies that render his opinions unreliable. Def. Mem. in Supp. of Mot. to Exclude Dr. Ashhab, at 6-9. In that deposition and in his report, Dr. Ashhab referred to her elevated aPTT score, 47, measured at least 24 hours, and likely 36 hours, after the Pradaxa was suspended due to the bleed. *Ex. 3 to Def.'s Mot. to Exclude Dr. Ashhab*, ECF No. 45-3, at 30-35;

Ex. 17 to Pls.' Resp. to Def. Mot. to Exclude Dr. Ashhab, at 3-5. Defendant cites to one of Plaintiffs' other experts who opined that an aPTT test result "cannot discriminate between above median therapeutic range and supra-therapeutic dabigatran levels." Def. Mem. in Supp. of Mot. to Exclude Dr. Ashhab, at 8; *Ex. 3b to Pls.' Resp to Mot. to Exclude Dr. Ashhab*, ECF No. 53-4, at 54. Defendant argues that this inconsistency between the Plaintiffs' experts establishes the unreliability of Dr. Ashhab's opinion that the aPTT result indicated Pradaxa-related over-anticoagulation. Def. Mem. in Supp. of Mot. to Exclude Dr. Ashhab, at 8-9.

Having read the full deposition transcript and considered the exhibits and argument offered by the parties, the Court disagrees with Defendant. Dr. Ashhab relied upon his extensive experience in concluding Ms. Knight was likely over-anticoagulated at the time of her bleed. See gener*ally Ex. 17 to Pls.' Resp. to Def. Mot. to Exclude Dr. Ashhab*. In his deposition, Dr. Ashhab explained that he considered the May 21 aPTT result, noting that it was measured after two or three doses had been skipped. *Ex. 3 to Def.'s Mot. to Exclude Dr. Ashh*ab, at 34-35. But he explained that Ms. Knight's aPTT readings must have been considerably higher when she received her regular doses both during the time that the bleed began, and while she continued to take her regular dose until she was treated for the bleed. Id.

However, Dr. Ashhab did not merely assert, unsupported, the relationship between aPTT results and Pradaxa-related over-coagulation. Instead, BI, itself, told doctors via Pradaxa's label that "the aPTT test provides an approximation of PRADAXA's anticoagulant activity." Ex. 2 to *Pls.' Resp. to Def.'s Mot. to Exclude Dr. Ashhab*, ECF No. 53-2, at 2. In order to draw a conclusion regarding Ms. Knight's Pradaxa-related over-anticoagulation, Dr. Ashhab used a test that BI told doctors to use to approximate Pradaxa's anticoagulant activity. *Ex. 3 to Def.'s Mot. for Summ. J.*, at 32-34 ("Q. So is it your position that any conclusion that you draw from [an aPTT] as to Ms.

Knight's over-anticoagulation is a guess? A. It's a guesstimate based on the best available information provided to me from the lab because I did not have any other way of measuring that *according to the drug manufacturer's recommendation. They don't give me anything* else. So I use what I have." (emphasis added)); *Ex. 2 to Pls.' Resp. to Summ. J.*, at 2 ("Bleeding risk can be assessed by the ecarin clotting time (ECT) . . . If ECT is not available, the aPTT test provides an approximation of PRADAXA's anticoagulant activity."). Where BI told doctors that the aPTT approximates the anticoagulant activity of Pradaxa, it cannot now argue that a doctor's opinion regarding too much anticoagulant activity is unreliable where it was based, in part, upon that test. The aPTT results, however, are not Dr. Ashhab's only basis for opining that Ms. Knight was over-anticoagulated.

Dr. Ashhab also noted that Ms. Knight's medical history and other medical conditions are known to substantially increase the risk of bleeding. *Ex. 17 to Pls.' Resp. to Def. Mot. to Exclude* Dr. Ashhab, at 4-5. And because those conditions increase the risk of bleeding, they are also recognized as affecting whether, or how much, Pradaxa should be prescribed. Id. In other words, Dr. Ashhab reviewed and considered Ms. Knight's complete medical record and the implications that record had on her bleed risk.

Upon his review, his medical experience and knowledge, and the results of an anticoagulant test that was recommended by BI in Pradaxa's label, Dr. Ashhab opined that Pradaxa contributed to Ms. Knight's over-anticoagulation. Id.; *Ex. 3 to Def.'s Mot. for* Summ. J., at 32-34; *Ex. 2 to Pls.'* Resp. to Summ. J., at 2. Indeed, even one of Defendant's experts agreed that Pradaxa contributed to Ms. Knight's bleed. *Ex. 4 to Pls.' Resp. to Def.'s Resp. to Summ. J.*, ECF No 53-5, at 2. In light of his considerations, Dr. Ashhab's opinion that the bleed in May 2013 – which indisputably

occurred – was causally connected to over-anticoagulation due to Pradaxa has an adequate medical foundation.

The record in this case further confirms Dr. Ashhab's conclusions. In response to Defendant's related motion to exclude evidence of plasma concentration levels, Plaintiffs supply considerable medical research, some from sources connected to Defendant, supporting the basis for Dr. Ashhab's conclusions. See generally Exs. 4, 5, 7-9, 17-21 *to Pls.' Resp. to Def.'s Plasma* Levels Mot., ECF Nos. 81-4, 81-5, 81-7–81-9, 81-17–81-22. That literature, most of which was generated or published prior to Ms. Knight's death, reflects a growing consensus that age, renal function, and concomitant use of other specific drugs greatly increases the risk of bleeding. Id. Further, high plasma concentration levels of Pradaxa are associated with an increased risk of bleeding, while not adding significantly to the prevention of stroke. *Ex. 4 to Pls.' Resp. to Def.'s* Plasma Levels Mot., at 6. The literature also recognizes that aPTT levels are a useful tool in determining plasma concentration levels in order to monitor and regulate Pradaxa use. Ex. 7 to *Pls.' Resp. to Def.'s Plasma Levels Mot.*, at 1; Ex. 8 *to Pls.' Resp. to Def.'s Plasma Levels Mot.*, at 3-5; see *Ex. 17 to Pls.' Resp. to Def.'s Plasma Levels Mot*. With the medical literature confirming the appropriateness of Dr. Ashhab's approach and conclusions, Defendant's attacks fall short.

Additionally, Defendant attempts to criticize Dr. Ashhab's opinions based upon his "guesstimate" of Ms. Knight's aPTT level at the time she reported the bleeding. *See Def.'s Mem.* in Supp. of Mot. to Exclude Dr. Ashhab, at 8-9. However, Defendant's argument simply mischaracterizes Dr. Ashhab's deposition testimony. In his report, Dr. Ashhab did not specify a particular aPTT estimate for Ms. Knight at the time of her bleed. *See generally Ex. 17 to Pls.'* Resp. to Def. Mot. to Exclude Dr. Ashhab. And in his deposition, Dr. Ashhab only "guessed" at specific numbers in response to defense counsel's questions. Id. at 32-36. It is clear from reading

Dr. Ashhab's deposition testimony that this "guess" was merely an illustrative example given to aid the clarity of his answers in response to defense counsel.

Relevantly, instead of merely opining upon "guesses," Dr. Ashhab criticizes the Pradaxa label precisely because BI neither recommended patient monitoring for possible over-anticoagulation, nor identified means to monitor anticoagulation through a Pradaxa concentration level test. *Ex. 3 to Def.'s Mot. to Exclude Dr. Ashhab*, at 32-33, 36. Indeed, a review of Pradaxa's label does not reveal any meaningful guidance given to doctors for the monitoring of anticoagulation through plasma concentration levels. *See Ex. 2 to Pls.' Resp. to Def.'s Mot. to* Exclude Dr. Ashhab. Therefore, Dr. Ashhab's opinion is admissible.

Dr. Ashhab provides an admissible causation opinion that attributes Ms. Knight's bleeding to Pradaxa, with regard to occurrence, severity, and persistence. Consistent with that opinion, Dr. Ashhab is also permitted to testify that had the additional warnings and instructions accompanied Pradaxa, Ms. Knight's treatment would have been different, diminishing the risk of bleeding and avoiding the role this medication played in her demise. Therefore, the Court **DENIES** Defendant's Motion to Exclude Dr. Ashhab.

Additionally, as explained below, because the Court separately rejects Plaintiffs' design defect claim related to the lack of a reversal agent, like Praxbind, Dr. Ashahb's opinions as to what would have occurred if a reversal were available are inadmissible.

b. Plasma Levels Motion

Defendant also seeks the exclusion of any evidence and argument related to "(1) the risk of bleeding posed by Pradaxa blood plasma concentrations above a specific level and (2) the alleged need to warn physicians to monitor patients' Pradaxa plasma concentrations." Def.*'s* Plasma Levels Motion, ECF No. 68, at 1. Generally, Defendant argues that evidence and argument

regarding the plasma concentrations should be excluded both because there is no evidence of Ms. Knight's blood plasma concentration at the time of her bleed, and because "there is no scientific support for Plaintiffs' proposals regarding the benefit of plasma concentration monitoring for Pradaxa patients." Id. However, Defendant's argument largely rehashes many of the same contentions that it made in its Motion to Exclude Dr. Ashhab. Id. at 4-5. Similar to the Court's decision regarding the Motion to Exclude Dr. Ashhab, the Court rejects Defendant's arguments for the exclusion of plasma concentration evidence and argument.

Contrary to the Defendant's argument, the record reflects ample support for Plaintiffs' proposals concerning plasma concentration monitoring. *See e.g. Ex. 4 to Pls.' Resp. to Def.'s* Plasma Level Mot., at 6. Indeed, even BI's own documents and internal communications recognized a potentially dangerous "cutoff value" of plasma concentration. *Ex. 6 to Pls.' Resp. to Def.'s Plasma Level Mot.*, ECF No. 81-6, at 2; Ex. 9 to Pls.*'* Resp. *to Def.'s Plasma Level Mot.*, at 1-7; *Ex. 34 to Pls.' Resp. to Summ. J.*, ECF No. 51-34, at 1-2; *Ex. 35 to Pls.' Resp. to Summ. J.*, ECF No. 51-35, at 1. Where Defendant has previously recognized both the dangerous implication of some plasma concentrations of Pradaxa, and the potential need for monitoring to ensure patient safety, it is incongruous for it to now contend that there is no science to support these positions.

Likewise, the Court dismisses Defendant's argument that evidence regarding plasma concentration should be excluded because no measurements of Ms. Knight's plasma concentration were taken at the time of her bleed. If anything, Defendant's argument illustrates one of Plaintiffs' central claims: that Defendant never provided doctors with guidance as to how to measure Pradaxa blood plasma concentration levels. Plaintiffs recognize that at the time of her major bleed, doctors did not take Ms. Knight's plasma concentration levels. Pls.*' Resp. to Def.'s Plasma Levels Mot.*, ECF No. 81, at 9-10. Indeed, Plaintiffs argue that had BI instructed doctors on how to test for the

blood plasma concentrations of Pradaxa, doctors would likely have been able to abate Ms. Knight's bleeding earlier, and prevent her rapid deterioration and eventual demise. Id. The Court will not allow Defendant to exclude evidence of a test when Defendant is potentially responsible for that test not being administered in this case.

Further, the aPTT testing performed around the time of Ms. Knight's bleed supports Plaintiffs' contention that she was likely over-anticoagulated. In addition to Dr. Ashhab's expert opinion on that point, Plaintiffs have also produced scientific literature showing the relationship between aPTT scores and over-anticoagulation, as measured by blood plasma concentration of dabigatran. *Ex. 17 to Pls.' Resp. to Def.'s Plasma Levels Mot.*, at 5-6. Given the relationship between the aPTT results and the blood plasma concentration levels, the Court finds that the existing medical record provides a sufficient basis for blood plasma concentrations to be relevant, admissible evidence. The Court **DENIES** Defendant's Plasma Levels Motion.

c. Foreign Label Motion

In its Foreign Label Motion, Defendant requests that the Court exclude any evidence, testimony, or argument concerning foreign regulatory actions regarding Pradaxa, foreign labels, or the Company Core Data Sheet ("Data Sheet") for Pradaxa. *Def.'s Foreign Label Mo*t., ECF No. 65, at 1. The foreign labels contain information and warnings about Pradaxa that BI gave to doctors and patients in different countries. The Data Sheet "summarizes the safety and efficacy statements [of Pradaxa], and it also represents the basis for the local labels on a worldwide basis." Ex. E to *Def.'s Foreign Label Mot.*, ECF No. 65-5, at 3. Defendant argues both that this line of evidence is irrelevant and that it is disproportionally prejudicial. Def.'s Foreign Label Mot., at 1.

With regard to relevance, Defendant contends the foreign labels and the Data Sheet apply to dosages not at issue in this case. Thus, Defendant argues that the labels and Data Sheet are

inapplicable to Ms. Knight's Pradaxa usage. *Def.'s Foreign Label Mot.*, at 5-6. Specifically, Defendant asserts that the European label concerns only doses of 110 mg or 150 mg of Pradaxa for A-Fib patients. Id. at 5. The only 75 mg dose of Pradaxa addressed by the European label is for prevention of embolism in patients who have orthopedic surgery. Id. Defendant contends that the risks associated with either dissimilar doses, or doses for different purposes, are not relevant to Ms. Knight's 75 mg Pradaxa dose for stroke prevention related to her A-Fib. Although true that the foreign labels do not recommend a 75 mg dose for A-Fib patients, the value of this evidence does not come from the exact dosing information.

The foreign labels and Data Sheet demonstrate Defendant's knowledge and beliefs regarding the bleed risks of Pradaxa. Importantly, the foreign labels and Data Sheet demonstrate that BI understood that a certain plasma concentration of Pradaxa posed a much greater danger of bleeding to patients. *Ex. 6 to Pls.' Resp. to Def.'*s Foreign Label Mot., ECF No. 82-6, at 5-7, 63-76; *Ex. 8 to Pls.' Resp. to Def.'*s Foreign Label Mot., ECF No. 82-8, at 35-37; *Ex. 14 to Pls.' Resp.* to Summ. J., at 4-7. The foreign labels and Data Sheet also demonstrate that BI knew that certain risk factors exponentially increased dabigatran absorption—thus increasing both the plasma concentration and the risk of major bleeding—and that BI knew the multiplier by which these risk factors affected Pradaxa absorption in those taking the medicine as recommended. Id. Furthermore, those documents show that that BI believed it necessary to not only provide a threshold plasma concentration level of dabigatran that patients should not exceed, but also that BI believed it necessary to recommend testing in patients with certain risk factors to ensure that dabigatran levels did not exceed the threshold. Id. The Court finds that this evidence is relevant, establishing what BI knew and believed regarding the bleed risks with certain patients on Pradaxa.

In its second argument for exclusion of the foreign labels and Data Sheet, Defendant warns that this evidence would confuse the jury. *Def.'s* Foreign Label Mot., at 7. Introducing evidence of foreign labels and the Data Sheet would "invite[] the jury to disregard the FDA's conclusions," and to instead depend upon foreign regulatory bodies. Id. at 9-10. As a result, so says Defendant, a "mini-trial" would ensue. Defendant asserts that if Plaintiffs were permitted to introduce evidence of foreign labeling, Defendant would "need to explain the differing regulatory histories and standards and show that the company complied with the requirements of foreign regulators." *Def.'s* Reply in Supp. of Foreign Label Mot., ECF No. 97, at 6-7. Defendant says that it would also have to explain "why information in the [Data Sheet] and on Pradaxa's product labeling around the world began to diverge . . . ." Id. Defendant submits that "[t]he Court should avoid these mini-trials." Id. The Court agrees that it should avoid these mini-trials, however, the Court disagrees that Plaintiffs' introduction of foreign labels or the Data Sheet will necessitate such mini-trials.

In the context of this litigation, where Plaintiffs contend that BI knew about enhanced risks, but failed to inform doctors and patients in West Virginia, the foreign labels and Data Sheet offer probative and valuable evidence of BI's knowledge and beliefs. And, where Plaintiffs' evidence suggests that BI may have never informed the FDA about some of the information regarding the heightened risk of bleeding, *see Ex. 33 to Pls.' Resp. to Summ. J.*, at 103, BI's knowledge and its conduct regarding that knowledge becomes even more pertinent.

The Court recognizes that an argument that BI must meet foreign labeling standards when warning patients and doctors in the United States may be impermissible. However, Plaintiffs have made clear that they seek to introduce this evidence to demonstrate what BI knew and believed. *See Pls.' Resp. to Def.'s* Foreign Label Mot., ECF No. 82, at 1-2. Due to Plaintiffs' allegation about a lack of specific information in the U.S. label and Medication Guide regarding multiple

aspects of the increased bleed risk associated with Pradaxa, the foreign label and Data Sheet have a high probative value for BI's knowledge and beliefs.

Simply, the danger of confusion, unfair prejudice, or misleading the jury does not substantially outweigh the probative weight of the evidence regarding foreign labels and the Data Sheet. See Fed. R. Evid. 403. Therefore, the Court **DENIES** Defendant's Foreign Label Motion (ECF No. 65). However, the Court will not permit the parties to devolve the trial into "mini-trials" over the foreign labeling standards. The parties should keep the argument regarding the foreign labels and the Data Sheet confined to BI's knowledge and beliefs. To the extent that the parties believe additional measures are necessary to address any likelihood of confusion or prejudice concerning the applicability of foreign labeling standards, those measures may be addressed by the instructions to the jury.

d. Reversal Agent Motion

Finally, Defendant requests that this Court preclude Plaintiffs from offering evidence of, or argument about, Pradaxa's lack of a reversal agent during the time that Ms. Knight took Pradaxa. *Def.'s Reversal Agent Mot.*, ECF No. 66, at 1. Defendant argues both that evidence regarding the lack of a reversal agent is irrelevant to Plaintiffs' claims and that that evidence is unduly prejudicial. Id. at 5-9.

As explained later in this Memorandum Opinion and Order, the Court grants summary judgment in favor of Defendant on Plaintiffs' defective design claim that is based upon the contention that Pradaxa should have had a reversal agent when Ms. Knight took the medication. However, Plaintiffs' claims regarding the failure to warn remain viable. To the extent that Plaintiffs' warnings claims involve an allegation that BI's warning that no reversal agent existed was inadequate, Plaintiff may elicit testimony and introduce evidence. But, because Plaintiffs'

defective design claim does not survive, evidence of either the lack of the reversal agent or the later development of the reversal agent, used to demonstrate the defective design of Pradaxa, will not be permitted. Therefore, the Court **DENIES**, **IN PART**, and **DENIES**, **AS MOOT**, the remainder of Defendant's Reversal Agent Motion (ECF No. 66).

B. Dispositive Motions

Turning to the dispositive motions, there are two pending: Defendant's Motion for Summary Judgment (ECF No. 42) and Plaintiffs' Motion for Partial Summary Judgment (ECF No. 44). As explained below, the Court finds that a majority of Plaintiffs' claims, with the exception of Plaintiffs' defective design claim premised upon the lack of a reversal agent and Plaintiffs' claim for breach of implied warranty of fitness, are better suited for a determination by a jury.

a. *Defendant's Motion for Summary Judgment*

Defendant vies for summary judgment in its favor on all of Plaintiffs' claims. Essentially, Defendant contends that the record fails to support any of Plaintiffs' claims.

As an initial matter, West Virginia law provides that strict liability defective product claims "fall into three broad, and not mutually exclusive, categories: [(1)] design defectiveness; [(2)] structural defectiveness; and [(3)] use defectiveness arising out of the lack of, or the adequacy of, warnings, instructions, and labels." Ilosky v. Michelin Tire Corp., 307 S.E.2d 603, 609 (W. Va. 1983) (quoting Morningstar v. Black & Decker Mfg. Co., 253 S.E.2d 666, 682 (W. Va. 1979)). These claims do not encompass the totality of product liability claims in West Virginia. A plaintiff may premise a product liability action "on three independent theories—strict liability, negligence, and warranty." Id. at 613. Because each theory has different elements to establish liability, "[n]o rational reason exists to require plaintiffs in product liability actions to elect which theory to submit

to the jury . . . ." Id. Consistent with the product liability claims permitted under West Virginia law, Plaintiffs have stated claims upon each of the three independent theories for liability.

In the interests of clarity, the Court will examine each category of claims, and the parties' respective arguments, in turn.

i. Failure to warn claims

As the Court detailed above, Plaintiffs' failure to warn claims fall into roughly three categories: (1) BI failed to include information regarding the higher risk of major bleeding events for patients who suffer from severe renal impairment and who take P-gp inhibitors, and BI's subsequent change to the label was inadequate because BI failed to bring that change to the attention of physicians and patients; (2) BI never warned patients or doctors that at a certain blood plasma concentration of Pradaxa, patients have an exponentially higher risk of bleeding, without any significant decrease in stroke risk, and BI should have instructed doctors to monitor, and how to monitor, patients' dabigatran concentration levels in their blood plasma; and (3) BI failed to provide specific information regarding the multiple increase in bleed risk associated with certain patient factors such as age, concomitant medications, and renal impairment. See supra pp. 11-12. Further, Plaintiffs contend that different, adequate warnings would have avoided Ms. Knight's injury. *Pls.' Resp. to Summ. J.*, ECF No. 51, at 5-11.

Defendant argues that summary judgment is appropriate on Plaintiffs' failure to warn claims[2] because (1) the Pradaxa labeling was adequate with regard to Ms. Knight, and (2) because

[2] As an aspect of its summary judgment motion, Defendant argues that the Court should dismiss "[a]ny claim that the Pradaxa label should have instructed physicians to prescribe a dose lower than what was approved by the FDA [because it] is preempted by federal law." *Def.'s Mem.* in Supp. of Mot. for Summ. J., at 6-7. Plaintiffs, however, have not advanced any such claim. Therefore, without needing to engage in the substance of that argument, the Court **DENIES**, **AS MOOT**, that aspect of Defendant's Motion for Summary Judgment.

"Plaintiffs' have no evidence that a different Pradaxa warning would have avoided Ms. Knight's injury." *Def.'s Mem. in Supp. of Mot. for Summ. J.*, ECF No. 43, at 7-14; *Def.'s Mot. for Summ.* J., ECF No. 42, at 1. The Court disagrees with both of Defendant's contentions. Accordingly, Plaintiffs' failure to warn claims should be determined by a jury.

In general, a "manufacturer is strictly liable for injuries caused by its products 'if the involved product is defective in the sense that it is not reasonably safe for its intended use.'" Waters v. Electrolux Home Prods., Inc., 154 F.Supp.3d 340, 351-52 (N.D.W. Va. 2015) (quoting Ilosky, 307 S.E.2d at 609). The touchstone for reasonable safeness is what standards a reasonably prudent manufacture should have abided by at the time the product was made. Ilosky, 307 S.E.2d at 609. Additionally, the plaintiff must demonstrate that the defect was the proximate cause of the alleged injury. Id.

In order to maintain a failure to warn claim under West Virginia law, also referred to as use defectiveness, a plaintiff must establish that the defendant breached a duty to warn. See Waters, 154 F.Supp.3d at 352. The plaintiff's use of the product must be foreseeable in order to give rise to a manufacturer's duty to warn. See Ilosky, 307 S.E.2d at 609. A determination that a product is unsafe arising from a failure to adequately warn depends upon "what the reasonably prudent manufacturer would accomplish in regard to the safety of the product, having in mind the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to the economic costs, at the time the product was made." Id. at 611 (quoting Morningstar, 253 S.E.2d at 682-83) (internal quotation marks omitted). Given a showing that a plaintiff used the product consistent with its intended use, "the determination of whether a defendant's efforts to warn of a product's dangers are adequate is a jury question." Id. at 611.

In the discussing the preliminary motions above, the Court noted much of Plaintiffs' evidence regarding the potential insufficiency of Defendant's warnings for Pradaxa. Not only has Plaintiffs' expert, Dr. Ashhab, opined that Ms. Knight's May 2013 gastrointestinal bleed "was caused or contributed to by her use of Pradaxa," *Ex. 1 to Pls.' Resp. to Summ. J.*, at 4, but even one of Defendant's experts concurred that Pradaxa contributed to Ms. Knight's bleed. Ex. 4 to *Pls.' Resp. to Def.'s Resp. to Summ. J.*, at 2. Dr. Ashhab also concluded that had BI "instructed Ms. Knight's physicians to measure dabigatran levels, and provided guidance on how to measure and interpret her dabigatran plasma concentration," the doctors would likely have found her levels to be elevated, and would have taken corrective action to lessen Ms. Knight's bleed risk. Ex. 1 to *Pls.' Resp. to Summ. J.*, at 5. Indeed, Dr. MacFarland's testimony confirms Dr. Ashhab's opinion that additional or different warnings would have affected the medical management of Ms. Knight. Dr. MacFarland testified that had BI recommended monitoring or identified additional testing, she would have used it in her treatment of Ms. Knight. *Ex. 8 to Pls.' Resp. to Summ. J.*, at 9-12.

Dr. Ashhab's opinions, coupled with Dr. MacFarland's testimony, at the very least demonstrate that had BI provided additional, different, or more detailed information in its Pradaxa label, Ms. Knight would have likely not been over-anticoagulated because both she and her doctors would have known that she had a high risk of developing a dangerous concentration of dabigatran. *Ex. 1 to Pls.' Resp. to Summ. J.*, at 4-5. With this knowledge, doctors could have monitored Ms. Knight's blood plasma, and thus substantially reduced the chance that she would have suffered a major bleed. Id. Finally, Dr. Ashhab concluded that the May 2013 bleed contributed to Ms. Knight's eventual death due to her inability to fully recover, and continued debility. Id. at 5.

Despite Dr. Ashhab's admissible expert opinion, Defendant contends that Pradaxa's label adequately warned Ms. Knight and her physicians of Pradaxa's risk and met the "reasonably

prudent manufacturer" standard. Defendant points out that the label noted that "**Pradaxa can cause serious and, sometimes, fatal bleeding**." *Def.'s Mem. in Supp. of Mot. for Summ. J.*, at 8 (emphasis original to memorandum). Additionally, Defendant asserts that the label contained "detailed information provided about the bleed rates seen in the 18,000-person RE-LY study," including warnings that elderly patients had a higher bleed risk, and that there was no reversal agent. Id. at 8-9. Defendant then cites the Medication Guide, which tells patients that there is a higher risk of bleeding in patients over 75, and that other medications may increase the bleed risk. Id. at 9. Finally, in contending that it provided adequate warnings, Defendant argues that its amended Pradaxa label is an adequate warning, at least with respect to one of Plaintiffs' warnings claims. *Def.'s Reply in Supp. of Mot. for Summ. J.*, at 2. Specifically, Defendant asserts that its addition of warning for people who both take P-gp inhibitors and have poor renal function, which it added roughly two months after Ms. Knight started taking Pradaxa, satisfies its duty to warn with respect to those issues. Id.

Citing both Dr. Ashhab's opinions, as well as BI's internal communications, scientific literature, and BI's foreign labeling information, Plaintiffs contend that Defendant's warnings were inadequate. Although BI provided a generalized warning regarding bleeding, Plaintiffs argued that due to the detailed risk-multipliers known by BI, it had a duty to warn patients like Ms. Knight who were not only elderly, but who also took concomitant medications, and had severe renal insufficiency. Additionally, Plaintiffs argue that BI's post-prescription amendment of Pradaxa's label also failed to meet BI's duty to warn Ms. Knight about the increased bleed risk for patients who both take P-gp inhibitors and have severe renal impairment. Plaintiffs have produced volumes of evidence supporting their positions, including Dr. Ashhab's report, scientific literature, BI's internal communications, and BI's foreign labeling information, most of which the Court has noted

in this opinion. Based upon this evidentiary showing—which because the evidence on the record has been discussed and cited throughout this opinion, the Court will not extensively detail again here—the Court finds that Plaintiffs' have viable warnings claims upon their multi-faceted allegations of inadequate warnings.

However, the Court will not make a decision regarding whether or not the Pradaxa warnings were adequate as a matter of law. Both parties have submitted evidence to support their respective positions, as the Court has discussed. Further, the Supreme Court of Appeals of West Virginia ("West Virginia Supreme Court") has instructed that "[t]he determination of whether a defendant's efforts to warn of a product's dangers are adequate is a jury question." Ilosky, 307 S.E.2d at 611. Mindful of the West Virginia Supreme Court's direction, and in light of sufficient evidentiary productions by both parties, the Court finds that the adequacy of Defendant's efforts to warn must be determined by a jury. See Johnson v. Fankell, 520 U.S. 911, 916 (1997) ("[T]he interpretation of [state law] by the [States' Supreme Court] would be binding on federal courts. Neither this Court nor any other federal tribunal has any authority to place a construction on [state law] different from the one rendered by the highest court of the State." (citations omitted)).

In addition to challenging the adequacy of the warnings, Defendant also argues that Plaintiffs have adduced no evidence that establishes that different warnings would have avoided Ms. Knight's injuries. *Def.'s Mem. in Supp. of Mot. for Summ. J.*, at 9-11. Defendant contends that Plaintiffs fail on the causation element of their warnings claims both because they have not shown that Ms. Knight ever read any Pradaxa warnings or labels, and because they cannot establish that additional information would have altered doctors' medical treatment of Ms. Knight. Id. Therefore, Defendant argues, Plaintiffs cannot show that that "a [different] warning would have made a difference." Id. at 10 (quoting Tracy v. Cottrell ex. rel. Cottrell, 524 S.E.2d 879, 891 n.9 (W. Va.

1999)). Furthermore, Defendant maintains that the difference must reflect a change "in a manner which would have avoided [the plaintiff's [sic] injury]." Id. at 11 (alterations original to memorandum) (quoting Mead v. Parsley, No. 2:09-cv-00388, 2010 WL 4909435, at *10 (S.D.W. Va. Nov. 24, 2010) (Copenhaver, J.)). But, the Court disagrees Defendant's arguments on causation.

First, the evidentiary record rebuts Defendant's argument that Ms. Knight did not read the Pradaxa warnings. Ms. Claudia Stevens, Ms. Knight's daughter, testified that Ms. Knight had a three-drawer plastic storage container in which she kept her medications and the information that came with them. *Ex. 10 to Def.'s Mot. for Summ. J.*, ECF No. 42-10, at 3-4. Although Ms. Stevens could not confirm whether or not Ms. Knight read the Pradaxa label, Ms. Steven's brother, Claude Knight, did provide insightful testimony on this issue. Mr. Knight confirmed that Ms. Knight read drug labels. *Ex. 11 to Def.'s Mot. for Summ. J.*, ECF No. 42-11, at 4-5. Mr. Knight testified that his mother, Ms. Knight, "pointed things [from the labels] out" to him. Id. In fact, on at least one occasion, Mr. Knight recalled his mother pointing out a side effect of a drug that she took. Id. at 5. That Ms. Knight kept medication labels, and that she was known to have read drug labels, meets the evidentiary burden for that question to survive summary judgment. Although the evidence is not clear cut, the record demonstrates more than a scintilla of evidence. That is all that is necessary for the question to go to the jury. See Anderson, 477 U.S. at 252.

Secondly, Plaintiffs adduced evidence showing that had BI provided additional information and warnings, Ms. Knight's doctors would have taken additional precautions and performed different testing. Dr. MacFarland not only testified that she would have liked to have known about the additional bleed risk information, such as characteristic-based increases in Pradaxa absorption, but she also testified that BI neither told her to perform Pradaxa concentration

testing, nor how to conduct such a test if she wanted to. Ex. 8 *to Pls.' Resp. to Summ. J.*, at 9-12. Further, Dr. MacFarland asserted that information about the exponential increase in bleed risk due to certain characteristics, such as age and renal function, would have affected her treatment decisions with regard to Ms. Knight's Pradaxa. Id. Finally, Dr. MacFarland agreed that had BI told her about this risk information and given her a measurement protocol regarding the blood plasma concentration of Pradaxa, she would have altered her medical management of Ms. Knight. Id. at 11-12.

Seeking to sow doubt upon the hypothetical effect of different warnings, Defendant focuses upon the testimony of two of Ms. Knight's other treating physicians. Defendant notes that Dr. Skuli Gunnalaugsson, a cardiologist who treated Ms. Knight, recorded in Ms. Knight's medical chart that she was well-managed from a bleeding and stroke-prevention perspective on August 29, 2013. *Def.'s Mem. in Supp. of Mot. for Summ. J.*, at 12. So too, Defendant cites to the testimony of Dr. Abdelgaber, another of Ms. Knight's treating physicians, who believed that "it was appropriate for [Ms. Knight] to be taking Pradaxa," in light of her medical history. See id. at 13; *see also Ex. 6 to Def.'s Mot. for Summ*. J., ECF No. 42-6, at 3. However, Dr. Abdelgaber also testified that if BI had recommended a test to measure the anticoagulant effect of Pradaxa, he would have used it. *Ex. 6 to Def.'s Mot. for Summ. J.*, at 11-12. Defendant argues that although Dr. Abdelgaber's testimony, in addition to the testimony of the other treating physicians, indicates that the doctors may have used a recommended concentration-monitoring test, it does not establish that a different warning "would have avoided Ms. Knight's use of Pradaxa or her gastrointestinal bleed." *Def.'s* Mem. in Supp. of Mot. for Summ. J., at 13.

Likewise, Defendant cites to Meade v. Parsley, a case out of this District, in support of its contention that Plaintiffs have failed to show that the additional or different warnings would have

altered behavior and avoided Ms. Knight's injury. *See Def.'s Mem. in Supp. of Mot. for Summ. J.*, 10-13. In that case, the plaintiff and her treating physician both testified that neither of them ever read the label for the medication in question. Meade v. Parsely, No. 2:09-cv-00388, 2010 WL 4909435, at *2 (S.D.W. Va. Nov. 24, 2010) (Copenhaver, J.). Additionally, the plaintiff did not retain an expert to establish general causation for her claims. Id. at *5. The Court found, citing to the lack of an expert on general causation, that the plaintiff had failed to establish causation. Id. at *7-8. Then the Court continued, explaining that even if the plaintiff had a causation expert, her claims would still fail because the record clearly demonstrated, by way of both her and her doctor's testimony, that no one read the labels. Id. at *9-10. Therefore, differing warnings would not have changed the circumstances because no one would have read them. Id. Meade, however, differs greatly from this case. Thus, Defendant's reliance upon Meade does not convince this Court that it should reach the same result.

Simply, the evidence establishes questions of fact as to both whether Ms. Knight read the label, and whether her doctors would have altered her treatment, thereby avoiding her injuries. The situation in Meade was clear. The plaintiff and her doctor both testified unambiguously that they did not read the medication's label. Id. at *5. In this case, the facts lack that definitive element. Additionally, Plaintiffs here have escaped the elementary mistake committed by the Meade plaintiff. In addition to Dr. Ashhab's expert report, Plaintiffs have produced extensive reports and scientific literature to support their causative argument. See generally Exs. 1, 4, 12, 21, 25, & 33 *to Pls.' Resp. to Summ. J.* The Court believes that Plaintiffs' case avoids the critical shortcomings of the plaintiff's case in Meade. Therefore, the Court will not impose Meade's outcome upon Plaintiffs.

This leaves the Court with disputed evidence that could reasonably lead to differing conclusions. The Court cannot, as a matter of law, determine that additional or different warnings would have had no impact upon Ms. Knight's medical treatment, or that they would not have avoided her injuries. Indeed, based upon Dr. MacFarland's and Dr. Abdelgaber's testimony that they would have used a test recommended by BI to more accurately measure the anticoagulant activity caused by Pradaxa, a reasonable fact finder could conclude that the warnings would have affected Ms. Knight's treatment and prevented her severe bleed. The Court finds that Plaintiffs have met their burden to establish a question of fact regarding the casual element of their use defectiveness claims.

In sum, having found that Plaintiffs have sufficiently demonstrated evidence to survive summary judgment on each element of their failure to warn claims, the Court **DENIES** Defendant's Motion for Summary Judgment regarding those failure to warn, or use defectiveness claims.[3]

ii. Defective design claim

Defendant also argues that Plaintiffs' defective design claim should be dismissed. In order to demonstrate that Defendant's design of Pradaxa was defective, Plaintiffs rely upon the absence of Praxbind, the antidote to Pradaxa, at the time of Pradaxa's FDA approval and Ms. Knight's use of the drug. Defendant contends that Plaintiffs' theory inappropriately seeks to prove the defectiveness of one drug by citing the development of an entirely different drug. The Court agrees with Defendant, and as such **GRANTS** Defendant's Motion for Summary Judgment in its favor on Plaintiffs defective design claim.

[3] Because at least some of Plaintiffs' claims continue, the Court also **DENIES** Defendant's Motion for Summary Judgment with regard to Plaintiffs' wrongful death claim. *See Def.'s Mem.* in Supp. of Mot. for Summ. J., at 19.

Design defects, under West Virginia, exist when a "product is not reasonably safe for its intended use due to a specific design flaw." Tyree v. Bos. Sci. Corp., No. 2:12-cv-08633, 2014 WL 5320518, at *3 (S.D.W. Va. Oct. 17, 2014) (Goodwin, J.) (citing Philip Combs, Andrew Cooke, Modern Products Lability Law in West Virginia, 113 W. Va. L.Rev. 417, 425 (2011)). Breaking this assertion into elements, a "plaintiff must establish that (1) the product was not reasonably safe; (2) for its intended use; (3) due to a defective design feature; (4) which proximately caused the plaintiff's injury." Id. (citing Morningstar, 253 S.E.2d at 682-83).

Putting the other elements aside, Plaintiffs' argument concerning the defective design rests upon "the lack of any adequate methods to reverse the anticoagulant effect of Pradaxa." *Pls.' Resp.* to Summ. J., at 11. In an attempt to demonstrate this inadequacy, Plaintiffs "point[] to two issues: Praxbind's sole function, and how [BI] itself describes Praxbind." Id. at 14. Nearly all of Plaintiffs' defective design argument rests upon the development of Praxbind, or the lack thereof. See id. at 17. The Court, however, will not permit Plaintiff to maintain a design defect claim by relying upon the development of a separate biologic.

About five months ago, a District Court in the Middle District of Georgia dealt with this same issue. In Chambers v. Boehringer Ingelheim Pharm., Inc., the plaintiffs, who were represented by the same counsel as Plaintiffs in this case, argued that BI "failed to timely develop Praxbind, despite it being feasible for the company to do so well before Mr. Chambers suffered his fatal bleed in May 2014." No. 4:15-CV-00068 (CDL), 2018 WL 849081, at *13 (M.D. Ga. Jan. 2, 2018) (quoting plaintiffs' response). The court rejected the plaintiffs' argument. It concluded that the plaintiffs "may not establish a design defect of Pradaxa by pointing to the failure to develop Praxbind." Id. (italics orginial). Emphasizing that Praxbind required separate FDA approval from Pradaxa, the court clarified that "Praxbind is not part of Pradaxa's design." Id.

Additionally, the court noted that although Praxbind may have stopped Mr. Chamber's bleeding, "its absence certainly did not cause the bleed in the first instance." Id.

This Court agrees with both the reasoning and conclusion of the Chambers court. Aside from the potential preemption issues involved with Plaintiffs' argument, *see Def.'s Mem. in Supp.* of Mot. for Summ. J., at 17, this Court finds that the failure to develop a separate FDA-approved medication prior to the sale of a different FDA-approved medication does not constitute permissible evidence of a design defect. See Chambers, 2018 WL 849081, at *12-14. Accordingly, Plaintiffs' design defect claim fails.

iii. Remaining common law and statutory claims

In addition to the defective product claims, Defendant requests that this Court dismiss Plaintiffs' remaining claims alleging negligence, fraud, and warranty breaches. Defendant argues for summary judgment on the negligence and fraud claims "for the same reasons Plaintiffs cannot establish a strict liability claim." *Def.'s Reply in Supp. of Mot. for Summ. J.*, at 7-8; *see also Def.'s* Mem. in Supp. of Mot. for Summ. J., at 17-19. However, as this Court has explained, Plaintiffs' warnings claims will continue. Defendant has only argued for the dismissal of the fraud and negligence claims based upon the same rationale it used to attack the strict liability claims. Therefore, the Court rejects Defendant's argument, and **DENIES** Defendant's Motion for Summary Judgment regarding Plaintiffs' negligence and fraud claims.[4]

[4] Additionally, Defendant argues for the dismissal of Plaintiffs' negligence per se claim based upon federal preemption. Defendant notes that "any tort claim premised solely on an alleged violation of the Federal Food, Drug, and Cosmetic Act is preempted by federal law." *Def.'s Mem.* in Supp. of Mot. for Summ. J., at 18-19 (citing Perdue v. Wyeth Pharm., Inc., 209 F.Supp.3d 847, 851 (E.D.N.C. 2016)). Consistent with Defendant's legal contention, Plaintiffs submitted that they "agree not to pursue recovery solely for violations of the FDCA, but believe evidence of such violations is proper and may be considered by the jury in support of Plaintiffs[']s other claims." *Pls.' Resp. to Summ. J.*, at 16 n.70 (underlining original). Plaintiffs' stipulation moots Defendant's argument for dismissal. Because "a plaintiff may bring a state law claim for conduct also in

Regarding Plaintiffs' warranty claims, Defendant argues that Plaintiffs' claims fail to meet the statutory requirements under West Virginia law. Plaintiffs have stated three warranty claims, one express warranty claim and two implied warranty claims. The two implied warranty claims are based upon the implied warranty of merchantability and the implied warranty of fitness. Encapsulated within a total of two paragraphs of briefing, Defendant summarily contends that the implied warranty claim—Defendant did not differentiate between Plaintiffs' two implied warranty claims, and instead apparently condensed them into a single claim—fails because it is inconsistent with the statutory definition of the claim.

Citing Keffer v. Wyeth, a case from this District, Defendant argues that the implied warranty claim—failing to differentiate between the two implied warranty claims—fails because "W. Va. Code § 46-2-315 'requires a particular purpose that differs from the ordinary purpose for which the goods are generally used.'" *Def.'s Mem. in Supp. of Mot. for Summ. J.*, at 18 (citing Keffer v. Wyeth, 791 F.Supp.2d 539, 547 (S.D.W. Va. 2011) (Copenhaver, J.)). As the court in Keffer made clear, that requirement applied only to a claim for breach of the implied warranty of fitness. See Keffer v. Wyeth, 791 F.Supp.2d 539, 546-47 (S.D.W. Va. 2011) (Copenhaver, J.). Judge Copenhaver found that the plaintiff in Keffer had failed to state a claim for breach of the implied warranty of fitness because the plaintiff had used the drug for "the ordinary, rather than particular, purpose." Id. at 547. Similarly, in this case, the record reflects that Ms. Knight took Pradaxa for its ordinary, intended use, and not for some peculiar or particular purpose. See id. at 546-47; Mullins v. Ethicon, Inc., No. 2:12-cv-02952, 2017 WL 319590, at *2 (S.D.W. Va. Jan. 20, 2017)

violation of the FDCA," the Court also **DENIES** Defendant's Motion for Summary Judgment to the extent that Plaintiffs keep to the confines of their stated use of the actions that are also violations of the FDCA. See Perdue v. Wyeth Pharms., Inc., 209 F.Supp. 847, 851 (E.D.N.C. 2016).

(Goodwin, J.) (citing W. Va. Code § 46-2-315). Therefore, the Court **GRANTS** Defendant's Motion for Summary Judgment on Plaintiffs' claim for breach of implied warranty of fitness.

However, the requirement cited by Defendant does not apply to a claim for breach of the implied warranty of merchantability. Section 46-2-314 of the West Virginia Code provides that "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." W. Va. Code § 46-2-314(1). Consistent with this statutory instruction, "merchantable" goods must be "fit for the ordinary purposes for which such goods are used . . . and adequately contained, packaged, and labeled as the agreement may require." Keffer, 791 F.Supp.2d at 542 (internal quotations and citations omitted) (citing W. Va. Code § 46-2-314(2)). Indeed, Judge Copenhaver noted, in Keffer, that "courts have recognized that claims for strict liability and breach of the implied warranty of merchantability are essentially coextensive in products liability actions." Id. at 545. Because the Court has already found that Plaintiffs have sufficiently supported their failure to warn claims, the Court similarly finds that Plaintiffs have produced enough evidence to continue with their claim for breach of the implied warranty of merchantability. See id. at 544-46; Raab v. Smith, 150 F.Supp.3d 671, 700 (S.D.W. Va. 2015) (Johnston, J.) ("The Court . . . determines that, for the same reasons Plaintiffs have sufficiently stated a claim for strict products liability based on the alleged defective [medical] devices, they have also stated a claim for breach of the implied warranty of merchantability."). The Court **DENIES** Defendant's Motion for Summary Judgment regarding Plaintiffs' claim for breach of implied warranty of merchantability.

Turning to Plaintiffs' express warranty claim, Defendant vies for its dismissal based upon Plaintiffs' failure to "identif[y] any warranty relied on." *Def.'s Mem. in Supp. of Summ. J.*, at 18. As with the implied warranty claims, express warranty claims are a statutory creation. West

Virginia Code instructs that "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." W. Va. Code § 46-2-313(1)(a). To maintain an express warranty claim, "no particular reliance on such statements need be shown in order to weave them into the fabric of the agreement." Tyree v. Bos. Sci. Corp., No. 2:13-cv-08633, 2014 WL 5359008, at *5 (S.D.W. Va. Oct. 20, 2014) (Goodwin, J.) (citing W. Va. Code § 46-2-313 (ed. note 3)).

Contrary to Defendant's concise argument, the Court finds that Plaintiffs have adduced enough evidence to proceed with their express warranty claim. As noted above, not only did Ms. Knight and her children seek out Pradaxa based upon BI's marketing and commercials, but the evidence also creates a genuine issue of fact as to whether Ms. Knight read the materials given to her regarding Pradaxa. The record sufficiently presents a genuine issue of fact as to whether an express warranty existed, and whether the breach of that warranty caused Ms. Knight's injuries. See Tyree, 2018 WL 5359008, at *5. Thus, the Court **DENIES** Defendant's Motion for Summary Judgment concerning Plaintiffs' express warranty claim.

iv. Punitive Damages

In West Virginia, in order to establish entitlement to punitive damages, a plaintiff must show that the "wrongful act [was] done maliciously, wantonly, mischievously, or with criminal indifference to civil obligations." Peters. v. Rivers Edge Mining, Inc., 680 S.E.2d 791, 821 (W. Va. 2009). Within the context of a products liability suit, the plaintiff demonstrates the appropriateness of punitive damages "by showing that the manufacturer, having actual or constructive knowledge of the product defect, continued to manufacture and distribute it." Eskridge v. Pacific Cycle, Inc., 556 Fed. Appx. 182, 192 (4th Cir. Jan. 17, 2014) (unpub.) (citing

Davis v. Celotex Corp., 420 S.E.2d 557, 559-61 (W. Va. 1992)). Specifically, for warnings claims, the plaintiff must produce evidence that shows that the defendant "had actual or constructive knowledge that [its] warnings were not sufficient." Id. (citing Ilosky, 307 S.E.2d at 619). Defendant claims that because Plaintiffs have shown no defect, and because it "provided clear and explicit warnings about the risk of bleeding," Plaintiffs' punitive damages claim fails.

The Court, however, believes that the record sufficiently presents evidence that raises a genuine issue of fact as to whether Defendant had actual or constructive knowledge of the insufficiency of Pradaxa's warnings. Rebutting Defendant's argument, Plaintiffs rehash the litany of scientific literature, BI internal communications, and Pradaxa's foreign labels to show that Defendant had the requisite knowledge of Pradaxa's insufficient warnings. *Pls.' Resp. to Summ.* J., at 19-21. The Court, having cited those portions of the record throughout this opinion, finds that the evidence suggests that Defendant may have had knowledge about the inadequacy of the warnings. Not only did the internal communications indicate recognition of the potential need for monitoring, but also Pradaxa's foreign labels reflected a clear understanding of the extent of the bleed risk. Further, because the Court has found that a genuine issue of material fact exists as to the adequacy of the warnings, the Court similarly finds a genuine issue of material fact concerning Defendant's knowledge of the warnings' adequacy. Therefore, the Court **DENIES** Defendant's Motion for Summary Judgment on Plaintiffs' punitive damages claim.

b. *Plaintiffs' Motion for Partial Summary Judgment*

In addition to Defendant's summary judgment motion, Plaintiffs also moved for partial summary judgment. Plaintiffs' motion, however, only concerned their defective design and failure to warn strict liability claims. *Pls.' Mot. for Partial Summ. J.*, ECF No. 44, at 2.

Without the need for extensive discussion, the Court rejects Plaintiffs' motion. As explained above, this Court granted summary judgment on the defective design claim in Defendant's favor. And this Court found that genuine issues of material fact existed as to Plaintiffs' failure to warn claims. Therefore, summary judgment upon these claims would be inappropriate. The Court **DENIES** Plaintiffs' Motion for Partial Summary Judgment (ECF No. 44).

IV. CONCLUSION

Based upon the forgoing, the Court:

1. **GRANTS** Defendant's Motion for Summary Judgment (ECF No. 42) only with regard to Plaintiffs' claims for defective design and breach of implied warranty of fitness, and **DENIES** the remainder of Defendant's Motion for Summary Judgment;
2. **DENIES** Plaintiffs' Motion for Partial Summary Judgment (ECF No. 44);
3. **DENIES** Defendant's Motion to Exclude Case-Specific Testimony of Dr. Hazem Ashhab (ECF No. 45);
4. **DENIES** Defendant's Motion in Limine No. 6 to Exclude Evidence and Argument Regarding Plasma Concentration Levels (ECF No. 68);
5. **DENIES** Defendant's Motion in Limine No. 3 to Exclude Evidence, Testimony, or Argument Related to Foreign Regulatory Actions, Foreign Labeling Materials and Company Core Data Sheet (ECF No. 65); and
6. **DENIES** Defendant's Motion in Limine No. 4 to Exclude Evidence and Argument Regarding Lack of Reversal Agent (ECF No. 66) to the extent that Plaintiffs' warnings claims allege that BI inadequately warned that no reversal agent existed, and **DENIES**, **AS MOOT**, the remainder of the motion.

The Court **DIRECTS** the Clerk to send a copy of this Memorandum Opinion and Order to counsel of record and any unrepresented parties.

ENTER: May 31, 2018

ROBERT C. CHAMBERS
UNITED STATES DISTRICT JUDGE