IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA

VIRGINIA CHAMBERS, SURVIVING SPOUSE OF BOBBY LEE CHAMBERS, ON BEHALF OF ALL LEGAL HEIRS OF BOBBY LEE CHAMBERS; AND VIRGINIA CHAMBERS, EXECUTOR OF THE ESTATE OF BOBBY LEE CHAMBERS,	**Civil Action Number: 4:15-cv-68 (CDL)**
Plaintiffs,	
v.	**JURY TRIAL DEMANDED**
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	
Defendant.	

JOINT PRETRIAL ORDER

This case is scheduled for a jury trial to begin on December 3, 2018 at 9:00 A.M. at the United States Courthouse in Columbus, Georgia. The following constitutes a pretrial order entered in the above-styled case after conference with counsel for the parties:

(1) (a) The names, addresses, and telephone numbers of all attorneys who personally appeared at pretrial and who will conduct the trial are as follows:

Plaintiff: Jason Branch, C. Andrew Childers, Neal Moskow, Russell Abney, Emily Acosta.

Defendant: Paul W. Schmidt, Covington & Burling LLP, 620 Eighth Ave, Suite 4225, New York, NY 10018, (PH: 212-841 1171); Sharla J. Frost, Tucker Ellis LLP, 405 Main Street, Suite 1000, Houston, TX 77002 (PH: 281-657-0731); Eric E. Hudson, 6075 Poplar Avenue, Suite 500, Memphis, TN 38119; Ben J. Scott, 6075 Poplar Avenue, Suite 500, Memphis, TN 38119; Neal J. Callahan, Waldrep, Mullin & Callahan, LLC, 111 Twelfth Street, Suite 300, P.O. Box 351, Columbus, Georgia 31902 (PH: 706-320-0600).

Other: None

(b) The names, addresses, and telephone numbers of all nonparty persons including attorneys who have a fixed or contingent financial interest in this case are as follows:

Plaintiff: Childers, Schlueter & Smith, LLC; Philips Branch & Hodges.

Defendant: None.

(2) (a) Companion cases pending in this and other federal/state courts are: there are more than 2,800 Pradaxa injury cases pending in various state and federal courts around the country. The bulk of cases are currently pending in coordinated state-court proceedings in Connecticut and California. *See McDevitt v. Boehringer Ingelheim Pharm., Inc.*, No. CPL HHD-CV-15-6057664-S (Conn. Super. Ct.); *In re Pradaxa Cases*, No. CJC-16-004863 (Cal. Super. Ct.).

(b) Possible derivative claims not now the subject of pending litigation: None to the parties' knowledge.

(3) The estimated time required for trial is:

Plaintiff's Position: 10 days.

Defendant's Position: Defendant anticipates that trial of this case can be completed in the two weeks that the Court has set aside, provided that the Court grants equal time to both parties. Nonetheless, Defendant has serious concerns over whether Plaintiff intends to try her case in the ten days allotted, given that Plaintiff has (1) affirmatively designated approximately 18 hours of deposition testimony (not including Defendant's affirmative or counter-designations), and (2) listed thirty-three potential trial witnesses, including one witness (Dr. Laura Plunkett), whose testimony in each of the first two Connecticut bellwether trials has spanned three full days.

(4) The parties agree that the court has jurisdiction of the parties and the subject matter -- 28 U.S.C. § 1332, 28 U.S.C. §1367, and 28 U.S.C. § 1391(b)(2).

(5) The jury will be qualified as to relationship with the following: Virginia Chambers; Boehringer Ingelheim Pharmaceuticals, Inc.; all attorneys and law firms identified in Paragraph 1; and all witnesses identified in Paragraph 18.

(6) All discovery has been completed, unless otherwise noted, and the court will not consider any further motions to compel discovery except for good cause shown. The parties, however, shall be permitted by agreement to take depositions of any person(s) for the preservation of evidence or for use at trial.

By Defendant: Defendant also reserves the right to seek the Court's permission to depose (1) any treating physician to explore Plaintiff's one-sided communications with the physician, and (2) any fact witness listed in Paragraph 18(b) that has not already been deposed in this proceeding.

By Plaintiff: As noted above, the fact witnesses listed in Paragraph 18(b) below were identified by Plaintiff in her Initial Disclosures almost two years before the close of Fact Discovery in this case. Defendant never sought to depose most of such witnesses during Fact Discovery, and should not be permitted to reopen discovery to do so at this point.

(7) Unless otherwise noted, the names of the parties as shown in the caption to this order are correct and complete, and there is no question by any party as to the misjoinder or non-joinder of any parties.

(8) The following is the plaintiff's brief and succinct outline of the case and contentions:

Plaintiff: Bobby Lee Chambers was born in Macon, Georgia on January 6, 1928, as a child moved to Columbus, Georgia, and graduated from Jordan High School in Columbus, Georgia in 1945. Mr. Chambers was married to Virginia Chambers on August 15, 1945, and together they had two daughters, Connie and Debbie and a son, Howell. Mr. Chambers served in the U.S. Army during World War II, and was then a member of the National Guard Reserves. Mr. Chambers

worked in the dairy business for 37 years, starting out as a milk delivery man and working his way up to area manager. After he retired from the dairy business, Mr. Chambers went to work for the Muscogee County Sheriff's Office in 1991 as a bailiff in the Muscogee County Courthouse, where he continued to work up until his death.

Mr. Chambers was diagnosed with an irregular heartbeat called atrial fibrillation in January 2013, and was prescribed Pradaxa 150 mg BID for anticoagulation at that time. Pradaxa, as an anticoagulant, does not correct atrial fibrillation, but rather is given prophylactically to atrial fibrillation patients for stroke prevention. At all times during which Mr. Chambers took Pradaxa, the U.S. label instructed his physicians that "[g]enerally, the extent of anticoagulation does not need to be assessed." During that same time, the Pradaxa label in Europe and other countries instructed physicians that "the measurement of dabigatran related anticoagulation may be helpful to avoid excessive high exposure to dabigatran in the presence of additional risk factors." Because Boehringer did not disclose these additional risk factors in the U.S. Pradaxa label, Mr. Chambers took Pradaxa in the presence of additional risk factors, including his age, kidney impairment, and concomitant medications.

At the time he was prescribed Pradaxa, Mr. Chambers was 85 years old, and he had a glomerular filtration rate (GFR) of 55 mL/min/1.73. Using the Cockcroft-Gault formula, Mr. Chambers' creatinine clearance at that time was 52 mL/min.[1]

There was no information in the Pradaxa label at that time (or to this day for that matter) informing patients or physicians that the blood plasma concentration of Pradaxa in patients over

[1] The U.S. Pradaxa label does not tell patients or physicians that the patient's renal function should be determined by calculating creatinine clearance (CrCl) using the Cockroft-Gault formula that was utilized in the Pradaxa clinical trial (RE-LY). Boehringer provides that instruction, however, to patients and physicians in the rest of the world. GFR is an estimate of renal function that may differ materially from CrCl.

the age of 80 is two times higher than in non-elderly patients. Likewise, there was no information in the Pradaxa label then (or now) informing patients or physicians that the blood plasma concentration of Pradaxa in patients with moderate renal impairment is three times higher than in patients with normal kidney function. Boehringer's own analysis of the data from its Pradaxa clinical trials showed that "[t]here was a more than 2-fold increase in dabigatran exposure in patients aged 80 years or more compared to non-elderly patients, an about 3-fold increase in patients with moderate renal impairment (CrCL 30-50 mL/min) compared to patients without renal impairment."

As a result, neither Mr. Chambers nor his physicians were aware that his age and his degree of renal impairment would cause him to have significantly increased Pradaxa plasma concentrations in his blood. Both Shane Darrah, M.D. and Michael Sims, M.D., the physicians who prescribed Pradaxa to Bobby Lee Chambers, testified that had they known of the increased Pradaxa blood level in a patient like Mr. Chambers, they would have utilized that information in performing their risk-benefit analysis when deciding whether or not to prescribe Pradaxa to a patient like Mr. Chambers.

At the time he was prescribed and took Pradaxa, Bobby Lee Chambers was concomitantly taking aspirin 325 mg daily, and naproxen 500 mg (an NSAID medication)—each of which carries its own increased risk of bleeding. Although the U.S. Pradaxa label notes that the risk of bleeding is increased in patients concomitantly taking Pradaxa and antiplatelet and/or NSAID medications, the label did not (and still does not) contain any information as to what extent concomitant use increased the overall, synergistic bleed risk. In Europe and other countries around the world, Boehringer has informed physicians and patients for years that:

- Use of aspirin or Plavix approximately doubles the rate of major bleeding in Pradaxa patients; and
- Chronic use of NSAIDs increase the risk of bleed by approximately 50% in Pradaxa patients.

Again, Pradaxa's U.S. label did not inform Bobby Lee Chambers or his healthcare providers of the true extent of the risks that taking Pradaxa posed to patients like him.

Mr. Chambers was also taking carvedilol (brand name Coreg) during the time he was prescribed Pradaxa. Mr. Chambers' carvedilol prescription was increased from 3.125 mg per day (taken as ½ tablet twice per day) to 12.5 mg per day (taken as 1 6.25 mg tablet twice per day) when he began taking Pradaxa. Although the Pradaxa label informed physicians that P-gp inhibitor medications were likely to increase the concentration of Pradaxa in a patient's blood, at no time did the Pradaxa label inform physicians that carvedilol is a P-gp inhibitor, despite the fact that is one of the most common medications prescribed to cardiology patients. The Pradaxa label did, however, specifically list several other P-gp inhibitor drugs by name in relation to their potential interaction with Pradaxa.

On May 19, 2014, Mr. Chambers presented to the Emergency Department at St. Francis Hospital complaining of bright red rectal blood. He reported that he had passed black stools the previous day beginning after he returned home from church, that they had progressed to bright red blood, and that he had last taken a dose of Pradaxa the evening of May 18, 2014. Mr. Chambers also reported that he felt weak and lightheaded. The physicians at St. Francis admitted Mr. Chambers and diagnosed him with a gastrointestinal bleed.

At the time of admission, Mr. Chambers' creatinine serum was elevated at 1.7 mg/dL. Using the Cockcroft-Gault formula, Mr. Chambers' creatinine clearance at that time was 35

mL/min. Mr. Chambers' activated partial thromboplastin time (aPTT) on May 19, 2014 (measured at 6:48 a.m.) was elevated at 88.3 seconds, and his hemoglobin was low at 7.5 g/dL.

Shortly after being admitted to the hospital, Mr. Chambers received a gastrointestinal consultation, including an esophagogastroduodenoscopy, which showed no signs of upper GI bleed. On May 20, 2014, a nuclear bleeding scan was performed, which showed active bleeding in the splenic flexure in Mr. Chambers' colon.

Mr. Chambers' gastrointestinal bleed could not be stopped, and he continued to bleed. On May 21, 2014, he underwent an angiogram with coil embolization to attempt to stop the bleeding in his colon. Although the procedure appeared to have been successful at the time it was completed, Mr. Chambers bleeding continued after he was returned to his room. His aPTT was measured again at 11:31 a.m., on May 21, 2014, and was still elevated at 49.2 seconds, despite taking his last Pradaxa dose days prior. His creatinine serum level had also increased to 2.6 mg/dL, resulting in a creatinine clearance of 23 mL/min using the Cockcroft-Gault formula, and a diagnosis of acute renal failure. Mr. Chambers' hemoglobin had decreased to 7.2 g/dL.

Despite their continued efforts, the physicians at St. Francis were unable to stop Mr. Chambers' gastrointestinal bleed, and, as a result, he died at 2:28 p.m. on May 21, 2014. Prior to his death, he was transfused approximately 10 units of blood over a 48 hour period.

As a result of Boehringer's conduct and its defective drug, Pradaxa, Bobby Lee Chambers suffered severe and debilitating injuries, including death. Plaintiff brings the present action with theories of liability of strict liability – failure to warn, negligent failure to warn, strict liability –

design defect[2], along with a claim that Boehringer's conduct entitles her to an award of punitive damages.

(9) The following is the defendant's brief and succinct outline of the case and contentions[3]:

Defendant: Pradaxa (dabigatran) is an anticoagulant manufactured and marketed by BI to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. The first oral anticoagulant approved in over 50 years, Pradaxa was a breakthrough medical discovery that provided doctors a treatment alternative to warfarin, previously the sole option. Clinical studies demonstrated that Pradaxa 150 mg was superior to warfarin at preventing strokes and had a similar safety profile. On October 19 2010, the U.S. Food and Drug Administration approved Pradaxa for sale in the United States. For patients whose kidney function is not severely impaired, Pradaxa is administered in a single, 150 mg dose without the need for blood concentration monitoring.

In January 2013, at the age of 85, Bobby Lee Chambers was diagnosed with new onset atrial fibrillation. Mr. Chambers' cardiologist, Dr. Shane Darrah, prescribed him Pradaxa to reduce his risk of stroke. Based on Mr. Chambers' renal function, he was appropriately prescribed the 150 mg dose. Mr. Chambers was concomitantly taking aspirin, naproxen (an NSAID), and one or more P-gp inhibitors.

[2] Contrary to Boehringer's assertion otherwise, this Court has already ruled that Georgia law permits a plaintiff to pursue a design defect claim based on inadequate warnings in addition to a claim for negligent failure to warn. The Court reiterated that ruling at the pretrial conference held on November 1, 2018. *See* Doc. 51.

[3] Defendant objects to numerous statements in Plaintiff's outline of the case as irrelevant and factually inaccurate.

At all times during Mr. Chambers' Pradaxa usage, the FDA-approved prescribing information contained detailed warnings about the risk of bleeding. For instance, the Highlights section on the first page warned:

> **WARNINGS AND PRECAUTIONS**
> - Risk of bleeding: PRADAXA can cause serious and, sometimes, fatal bleeding. Promptly evaluate signs and symptoms of blood loss. (5.1)
>
> . . .
> - P-gp inducers and inhibitors: Effects on dabigatran exposure (5.4)
>
> . . .
> **ADVERSE REACTIONS**
> Most common adverse reactions (>15%) are gastric-like symptoms and bleeding (6.1)
>
> . . .
> **USE IN SPECIFIC POPULATIONS**
> Geriatric use: Risk of bleeding increases with age (8.5)

Elsewhere in the label, the prescribing information for Pradaxa contains additional warnings about bleeding, including warnings specifically about patients with Mr. Chambers' characteristics and co-medications:

> **WARNINGS AND PRECAUTIONS**
>
> **5.1 Risk of Bleeding**
>
> PRADAXA increases the risk of bleeding and can cause significant and, sometimes, fatal bleeding. Promptly evaluate any signs or symptoms of blood loss (e.g., a drop in hemoglobin and/or hematocrit or hypotension). Discontinue PRADAXA in patients with active pathological bleeding *[see Dosage and Administration (2.2)]*.
>
> Risk factors for bleeding include the concomitant use of other drugs that increase the risk of bleeding (e.g., anti-platelet agents, heparin, fibrinolytic therapy, and chronic use of NSAIDs). PRADAXA's anticoagulant activity and half-life are increased in patients with renal impairment *[see Clinical Pharmacology (12.2)]*.
>
> . . .
> **5.4 Effect of P-gp Inducers and Inhibitors on Dabigatran Exposure**
>
> . . .
> P-gp inhibition and impaired renal function are the major independent factors that result in increased exposure to dabigatran *[see Clinical Pharmacology (12.3)]*.

. . .

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

. . .

The risk of major bleeds was similar with PRADAXA 150 mg and warfarin across major subgroups defined by baseline characteristics, with the exception of age, where there was a trend towards a higher incidence of major bleeding on PRADAXA (hazard ratio 1.2, 95% CI: 1.0 to 1.4) for patients ≥75 years of age.

There was a higher rate of major gastrointestinal bleeds in patients receiving PRADAXA 150 mg than in patients receiving warfarin (1.6% vs. 1.1%, respectively, with a hazard ratio vs. warfarin of 1.5, 95% CI, 1.2 to 1.9), and a higher rate of any gastrointestinal bleeds (6.1% vs. 4.0%, respectively).

. . .

7 DRUG INTERACTIONS

. . .

P-gp inhibition and impaired renal function are the major independent factors that result in increased exposure to dabigatran *[see Clinical Pharmacology (12.3)]*.

. . .

8 USE IN SPECIFIC POPULATIONS

. . .

8.5 Geriatric Use

Of the total number of patients in the RE-LY study, 82% were 65 and over, while 40% were 75 and over. The risk of stroke and bleeding increases with age, but the risk-benefit profile is favorable in all age groups *[see Warnings and Precautions (5), Adverse Reactions (6.1), and Clinical Studies (14)]*.

The Pradaxa Medication Guide, which is written in patient-friendly language as a tool for physicians to help counsel patients and is dispensed by pharmacists directly to patients, also warned about the risk of bleeding, particularly in elderly patients and patients taking Mr. Chambers' other medications:

What is the most important information I should know about PRADAXA?

. . .

- PRADAXA can cause bleeding which can be serious, and sometimes lead to death. This is because PRADAXA is a blood thinner medicine that lowers the chance of blood clots forming in your body.

You may have a higher risk of bleeding if you take PRADAXA and:

- are over 75 years old

. . .

- take other medicines that increase your risk of bleeding, including:
    - aspirin or aspirin containing products
    - long-term (chronic) use of non-steroidal anti-inflammatory drugs (NSAIDs)

These prominent and extensive warnings adequately warned Dr. Darrah under Georgia law. Indeed, Dr. Darrah understood Pradaxa's bleeding risks and discussed them with Mr. Chambers. Dr. Darrah would not have altered his prescribing decision with different warnings.

On May 19, 2014, Mr. Chambers presented to the hospital with gastrointestinal bleeding. On May 21, Mr. Chambers successfully underwent coil embolization of his left colic artery to halt the bleed. Mr. Chambers passed away that same day from cardiac arrest. While any anticoagulant, including Pradaxa, can increase a patient's risk of bleeding, Pradaxa did not cause Mr. Chambers' arterial rupture or death.

(10) The issues for determination by the jury are as follows:

Plaintiff:

- Was Boehringer negligent in designing the drug Pradaxa?
- Was Boehringer negligent in failing to warn Bobby Lee Chambers' health care providers about the extent of the risks of which it knew or should have known to be related to Pradaxa, specifically the increased risk of bleeding in patients, like Bobby Lee Chambers?
- Is Boehringer strictly liable for the defective design of the drug Pradaxa?
- Is Boehringer strictly liable for failing to warn Bobby Lee Chambers' health care providers about the magnitude of the risks of which it knew or should have known to be related to Pradaxa, specifically the increased risk of bleeding in patients like Bobby Lee Chambers?
- Was Pradaxa a proximate cause of Bobby Lee Chambers' gastrointestinal bleed?

- Was Pradaxa a proximate cause of Bobby Lee Chambers' death?
- The amount of compensatory damages for pre-death claims to the Estate of Bobby Lee Chambers.
- The amount of wrongful death damages to Bobby Lee Chambers' surviving spouse and daughters.
- Has Boehringer acted in a manner such that punitive damages should be awarded, and, if so, in what amount?

Defendant:

(a) Whether, at the time Plaintiff's Pradaxa left Defendant's control, Defendant failed to provide an adequate warning to the learned intermediary of Pradaxa's potential dangers;

(b) Whether, at the time Plaintiff's Pradaxa left Defendant's control, Pradaxa's warnings were defective in design;

(c) Whether Defendant's alleged failure to warn or Pradaxa's defective design (inadequate warning) was the cause in fact of Plaintiff's injury;

(d) Whether Dr. Darrah would have prescribed Pradaxa to Plaintiff but for Defendant's allegedly inadequate or defective warning;

(e) Whether, by clear and convincing evidence, Defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care that would raise the presumption of conscious indifference to consequences; and

(f) Whether Plaintiff is entitled to compensatory or punitive damages and, if so, in what amount.

(11) If a tort action, specifications of negligence, including applicable code sections, are as follows:

Plaintiff: negligent failure to warn (O.C.G.A. § 51-1-2); strict liability - design defect due to inadequate warnings (O.C.G.A. § 51-1-11(b)(1)

Defendant: During the Pretrial Hearing, Plaintiff represented that she intends to pursue a single negligence claim (negligent failure to warn) and a single strict liability claim (design defect based on allegedly inadequate warnings). Boehringer is researching whether those two claims are entirely overlapping and, pursuant to the Court's direction at the Pretrial Hearing, will submit a brief in the event that Boehringer believes the two claims are materially identical.

(12) If a contract action, the terms of the contract are as follows (or, the contract is attached as an exhibit to this order): Not applicable.

(13) The types of damages and the applicable measure of those damages are as follows:

Plaintiff:

(1) Wrongful Death Damages (O.C.G.A. § 51-4-1 et seq.) – measurement is the full value of life to Bobby Lee Chambers to himself if he had lived, which has two components:

(a) those items having proven monetary value, such as lost potential lifetime earnings, income, or services; and

(b) lost intangible items whose value cannot be precisely quantified, such as Bobby Lee Chambers' loss of enjoyment of life, society, advice, example, and counsel, which also includes the loss to himself of the opportunity to be a family member to those who survived him;

(2) Pre-Death Damages (O.C.G.A. §§ 9-2-41 and 51-4-5(b)), which include funeral, medical, and other necessary expenses resulting from the injury and death of Bobby Lee Chambers, as well as

conscious physical and mental pre-death pain and suffering endured by Bobby Lee Chambers prior to his death;

(3) Punitive Damages (O.C.G.A. § 51-12-5.1), which is the amount necessary to punish, penalize, or deter the defendant – the measure of which may include:

(a) the nature and egregiousness (reprehensibility) of the defendant's conduct;

(b) the extent and duration of the defendant's wrongdoing and the possibility of its recurrence;

(c) the intent of the defendant in committing the wrong;

(d) the profitability of the defendant's wrongdoing;

(e) the amount of actual damages awarded;

(f) the financial circumstances, that is, the financial condition and or the net worth of the defendant; and

(g) any other pertinent circumstances.

Defendant: Defendant states that Plaintiff is not entitled to any damages.

(14) All material undisputed facts established by the pleadings, depositions, or admissions of the parties are attached hereto as **Exhibit A**, are signed by counsel, and will be submitted to the jury at the beginning of trial [ALL PARTIES MUST STIPULATE TO THESE FACTS - otherwise there are NO undisputed facts].

(15) Pursuant to the court's usual practice, pleadings will not be submitted to the jury.

(16) Special authorities relied upon by plaintiff relating to peculiar legal questions are as follows: Plaintiff notes that the Court has already ruled that her failure to warn claims (other than those related to approval of the 110 mg dose) are not preempted [Doc. 44], and Boehringer's argument to the contrary below is inappropriate for the trial of this case.

(17) Special authorities relied upon by defendant relating to peculiar legal questions are as follows:

(a) Learned Intermediary Doctrine: *Porter v. Eli Lilly and Co.*, 291 F. App'x 963, 964 (11th Cir. 2008) ("Under Georgia law, Porter was required to prove that, but for the alleged inadequate warning, Dr. Wolfberg, decedent's physician, would not have prescribed Prozac to decedent."); *see also Dietz v. Smithkline Beecham Corp.*, 598 F.3d 812, 816 (11th Cir. 2010) (no proximate causation where doctor "provided explicit, uncontroverted testimony that, even when provided with the most current research and FDA mandated warnings, he still would have prescribed Paxil for [the plaintiff's] depression"); *In re Mentor Corp. ObTape Transobturator Sling Prod. Liab. Litig.*, 711 F. Supp. 2d 1348, 1378 (M.D. Ga. 2010) (proximate causation inquiry focuses on whether the learned intermediaries "would have made the same decision to implant ObTape" in their patients).

(b) Federal Preemption: *Wyeth v. Levine*, 555 U.S. 555, 571 (2009) (state law failure-to-warn claim preempted where there is "clear evidence that the FDA would not have approved a change to [the medicine's] label"); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011) ("[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes."); *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 488 (2013) ("Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability.").

(c) Compliance with Governmental Regulations: *Doyle v. Volkswagenwerk Aktiengesellschaft*, 481 S.E.2d 518, 521 (Ga. 1997) (holding that "compliance with federal

standards or regulations is a factor for the jury to consider"); *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 675 (Ga. 1994); Ga. Pattern Civil Jury Instructions § 62.670; Federal Food, Drug, and Cosmetic Act.

(18) The following are lists of witnesses the:

(a) Plaintiff will have present at trial:

- Virginia Chambers
- Connie Bruner
- Debbie Michaelson
- Lawrence Baruch, M.D.
- Laura Plunkett, Ph.D.

(b) Plaintiff may have present at trial[4]:

- Shane Darrah, M.D.
- Michael Sims, M.D.
- William Fortson, M.D.
- Cameron Kersey, M.D.
- Linda Hodges, D.O.
- Cheryl A. Clark, M.D.
- Juan Amador, M.D.
- Jim Bruner, Sr.
- Jim Bruner, Jr.
- Bob Bruner
- Brittany Roop
- Thea Grice
- Todd Schuester
- Alison Schuester
- Todd Almond
- Gracie Almond
- Ann Lutz
- Pastor Bill Shorey
- Darrell Harris
- Teresa Harris
- Curtis Scott

[4] As noted above, the "may call" witnesses listed herein were all identified in Plaintiff's Initial Disclosures. Plaintiff is bringing a wrongful death claim, the measure of which in Georgia is the value of life to the decedent. Each of the damages witnesses called from the may call list will offer evidence to assist the jury in determining the value of Bobby Chambers' life, and will not be called to offer improper character evidence. The particular witnesses who will be called at trial will largely depend on their availability.

- Chris Scott
- Hon. John Allen
- Sheriff John Darr
- Joe Denson
- Brian Harvey, M.D.
- Robert Gosselin
- Glenn Chertow, M.D., MPH

(c) Defendant will have present at trial[5]:

- Stanley J. Schneller, M.D.

(d) Defendant may have present at trial:

- Klaus Dugi, M.D.;
- Charlie Mazzarella
- Maureen Oakes
- Charles S. Eby, M.D.;
- David J. Greenblatt, M.D.;
- H. David Humes, M.D.;
- Jörg Kreuzer, M.D.;
- Marianne C. Mann, M.D.;
- Michael J. Mello, M.D., M.P.H.;
- Paul Reilly, Ph.D.;
- C. Mel Wilcox, M.D.; and
- Any witness identified by Plaintiff in Paragraphs 18(a) and 18(b).

Opposing counsel may rely on representation by the designated party that it will have a witness present unless notice to the contrary is given in sufficient time prior to trial to allow the other party to subpoena the witness or obtain this testimony by other means. Counsel should be prepared to state at the pretrial conference objections to any witness listed.

[5] Defendant notes that Plaintiff's witness list is vastly over-inclusive for a ten-day trial. Defendant further notes that Plaintiff represented in her deposition that over half of the witnesses listed in Paragraph 18(b) do not possess any information regarding Mr. Chambers' medical treatment or healthcare decisions. Thus, any testimony would constitute improper character evidence.

(19) Attached hereto as **Exhibit B** is a list of all depositions that each party intends to introduce at trial. If parties do not intend to read the entire deposition into the record, page and line designations and counter designations should be included.

(20) Attached hereto as **Exhibit C** is a list of all exhibits that each party intends to tender into evidence at trial. [Please designate with an asterisk (*) those exhibits to which an authenticity objection exists.[6] All exhibits should be **numerically** marked prior to trial and should contain the following information: Case number and trial exhibit designation: P-1 would denote Plaintiff's Exhibit #1; D-1 would denote Defendant's Exhibit #1; J-1 would denote Joint Exhibit #1. Please DO NOT use letters to identify your exhibits. The courtroom deputy clerk will answer any questions regarding enumeration of exhibits and/or access to courtroom technology.] PLEASE NOTE: ELECTRONIC EVIDENCE FILES SHOULD BE PROVIDED TO THE COURTROOM DEPUTY ON THE FIRST DAY OF TRIAL, OR AS OTHERWISE ADVISED. PLEASE REFER TO THE COURT WEBSITE FOR

INFORMATION REGARDING THE JURY EVIDENCE RECORDING SYSTEM (JERS)

AND OTHER AVAILABLE COURTROOM TECHNOLOGY

(HTTP://WWW.GAMD.USCOURTS.GOV/TECHNOLOGY).

(21) Attached hereto as **Exhibit D** is the form of all possible verdicts to be considered by the jury.

(22) The possibilities of settling the case are:

By Plaintiff: Plaintiff has made a settlement demand to Defendant, but has not received any response to date.

[6] BI objects on authenticity grounds to Exhibit 2009.

By Defendant: BI recently received a settlement demand from Plaintiff. BI will respond in good faith.

(23) A jury of twelve will be selected and all jurors shall participate in the verdict unless excused from service by the court. Each side shall have 3 peremptory challenges.

(24) The parties are notified that if this action is settled after jurors have been summoned and it is too late to notify jurors that it is no longer necessary for them to report for jury service, the cost of compensating those jurors who report for jury service unnecessarily shall be taxed as costs upon the parties, as the Court determines appropriate.

(25) Other matters: The Parties have reached the following stipulations:

1. The parties stipulate to the admission of Bobby Chambers' medical records and bills.

2. The parties stipulate to the authenticity of any document authored by a BI employee that was produced by BI in this litigation and bears a Boehringer Bates number. Boehringer reserves the right to challenge whether a document is actually-company created, with the understanding that, generally speaking, emails and documents in custodial files are authentic subject to limited exceptions (such as handwritten notes by an unidentified author).

3. The party presenting a witness live on a given day of trial will notify the opposing party on a business day at least 36 hours prior to the start of trial that day. Such 36 hours' notice shall be given based on a 9:00 a.m. start time for trial (e.g., if the party intends to present a certain witness live at trial on Wednesday, that party will notify the opposing party no later than 9:00 p.m. the preceding Monday). The party presenting a witness by video deposition on a given day of trial will similarly notify the opposing party

on a business day at least 36 hours prior to the start of trial that day (subject to "filling in" as necessary, in which case the party presenting the witness by video deposition will provide at least 12 hours' advance notice, or less if by agreement).

4. The party presenting an expert witness on a given day of trial will similarly notify the opposing party on a business day at least 36 hours prior to the start of trial that day of the following information: additional reliance materials and an update on fees billed for general litigation and case-specific opinions. Notwithstanding the foregoing, the additional reliance materials are not to be used in a manner inconsistent with the expert witness disclosure requirements under the Federal Rules of Civil Procedure.

5. The parties agree that the testimony of any treating or prescribing physician witness in the case may be presented via deposition testimony in lieu of calling the witness live at trial, without the need for a finding of unavailability under Rule 32 of the Federal Rules of Civil Procedure.

6. The party presenting a witness will provide via email to the opposing party the proposed direct examination exhibits the party intends to use on a given day of trial by 7:00 pm the prior evening, and the opposing party will provide via email any objections to those exhibits by 7:00 am the following morning.

7. The parties will exchange slides and demonstrative exhibits via email by 8:00 a.m. on the morning of the trial day they intend to use them, absent unforeseen circumstances.

8. Plaintiff will not offer evidence, testimony, or argument regarding other lawsuits, claims, settlements, or verdicts involving Pradaxa or other Boehringer Ingelheim ("BI") products (including the *In re Pradaxa MDL* settlement); but each party reserves the

right to offer evidence of any civil or criminal agreements, judgments, investigations, or findings that may occur after November 22, 2017, and each party reserves the right to object to such evidence.

9. Plaintiff will not offer evidence, testimony, or argument regarding BI finances and sales/advertising figures with respect to products other than Pradaxa; and the price of products other than Pradaxa. Notwithstanding the foregoing, the parties have not reached agreement regarding the admissibility of evidence of BI's gross annual sales and profits, and Plaintiff reserves the right to offer such evidence during the punitive damages phase of trial, in the event the jury determines that punitive damages are appropriate.

10. Plaintiff will not offer evidence, testimony, or argument regarding criticisms or claims based on the lack of black box or boxed warnings in Pradaxa's label, or rely on the absence of specific information included in such warnings unless the Defendant puts the issue in evidence by raising the sufficiency of the black box or boxed warnings.

(26) Additional Other Matters:

Plaintiff:

(1) Plaintiff requests that she be entitled to introduce Boehringer produced documents meeting the requirements for admissibility under Rule 801 without a "sponsoring witness."

(2) Plaintiff urges adherence to Federal Rule of Civil Procedure 32(a)(6) and Federal Rules of Evidence 106 and 611 to limit the scope of deposition counter-designations and cross examinations to the scope of the deposition designation and direct examination.

(3) Plaintiff requests that any court ruling as to restriction of Plaintiffs' presentation of evidence should apply equally to the Defendant's presentation of evidence.

(4) Plaintiff has requested that Defendant stipulate to the admissibility of The Commissioners 1958 Standard Ordinary Mortality Table (Plaintiff's Ex. 2019), the Annuity Mortality Table for 1949, Ultimate (Plaintiff's Ex. 2020), and/or the American Experience Mortality Tables (Plaintiff's Ex. 2021). To the extent Defendant does not so stipulate, Plaintiff requests that the Court admit the America Mortality Tables pursuant to O.C.G.A. § 24-14-44, which states "[i]n all civil proceedings where the life expectancy of a person shall be an issue, the American Experience Mortality Tables shall be admissible as evidence of the life expectancy of such person." Plaintiff further requests that the Court admit The Commissioners 1958 Standard Ordinary Mortality Table and the Annuity Mortality Table for 1949, Ultimate, pursuant to O.C.G.A. § 24-14-45, which states that "In addition to any other lawful methods of computing the value of the life of a decedent in a wrongful death case or of determining the present value of future earnings or amounts in proceedings involving permanent personal injuries, there shall be admissible in evidence, as competent evidence in such proceedings, either or both of the following mortality tables: (1) The Commissioners 1958 Standard Ordinary Mortality Table and Annuity Mortality Table for 1949, Ultimate; or (2) Annuity Mortality Table for 1949, Ultimate."

Defendant:

(1) If punitive damages are permitted to go to the jury, Defendant submits that bifurcation is required. *See* Ga. Code Ann. § 51-12-5.1(d)(1)–(2) ("In any case in which punitive

damages are claimed, the trier of fact shall first resolve from the evidence produced at trial whether an award of punitive damages shall be made. . . . If it is found that punitive damages are to be awarded, the trial shall immediately be recommenced in order to receive such evidence as is relevant to a decision regarding what amount of damages will be sufficient to deter, penalize, or punish the defendant in light of the circumstances of the case."); *In re Mentor Corp. ObTape Transobturator Sling Prod. Liab. Litig.*, No. 3:07-CV-00101, 2010 WL 1998166, at *4 (M.D. Ga. May 18, 2010) ("[U]nder Georgia law, cases involving a claim for punitive damages must, at a minimum, be bifurcated.").

(27) Court's Rulings on Motions in Limine

The Court made several oral rulings at the pretrial conference held on November 1, 2018. Those rulings, along with rulings on motions in limine not argued orally, are summarized below.

I. Boehringer's Motions in Limine

1. 110-mg Dose (ECF No. 59)

Denied. Plaintiff may introduce 110-mg evidence to the extent it is probative of Boehringer's knowledge of the dangers of the 150-mg dose and whether Boehringer knew how to more robustly warn of the dangers of the 150-mg dose.

2. Pradaxa Blood Concentrations (ECF No. 60)

Denied.

3. Praxbind Regulatory History (ECF No. 62)

Granted.

4. Alternative Pradaxa Formulations (ECF No. 63)

Denied.

5. World War II History & Other Pradaxa Verdicts/Cases (ECF No. 64)

Granted. If Plaintiff determines that such evidence somehow becomes relevant at trial, counsel shall alert the Court outside the presence of the jury before seeking to admit the evidence.

6. Other Labeling Criticisms (ECF No. 65)

Granted.

7. Monitoring of Other Blood Thinners (ECF No. 66)

Denied.

8. Foreign Regulation of Pradaxa (ECF No. 67)

Deferred ruling to trial. Denied to the extent the Court has determined that some evidence regarding the 110-mg dose may be relevant and admissible to show knowledge of harm and ability to warn more robustly. Some of the foreign regulation evidence may be admissible for similar purposes.

9. MDL Discovery Abuses (Def.'s Mot. in Limine No. 9, ECF No. 68; Pl.'s Mot in Limine, ECF No. 61)

Boehringer's motion is granted. Plaintiff's motion for an adverse inference is denied.

10. Submission of Information to FDA (ECF No. 69)

Denied.

11. Boehringer Financial Information or Bifurcation (ECF No. 70)

Plaintiff may introduce financial evidence that is probative of Boehringer's alleged focus on profit over patient safety and narrowly targeted to show that such motivation influenced its decisionmaking regarding its warnings. But general financial information and information about Pradaxa's financial success is otherwise irrelevant in the liability phase of the trial and shall be excluded during that phase. The Court shall bifurcate the liability and punitive damages phases of the trial, and the evidence may be admissible in the punitive damages phase.

12. Deficiencies in Pradaxa Testing (ECF No. 71)

Denied.

13. BMJ Articles (ECF No. 72)

Deferred to trial when the Court can determine based on Plaintiff's expert's testimony whether the articles qualify as learned treatises for purposes of an exception to hearsay. The Court notes that Plaintiff has withdrawn two of the articles.

14. Failure to Develop Quantitative Assay (ECF No. 73)

Denied.

15. Dr. Plunkett Supplement (ECF No. 74)

Granted. If Plaintiff wishes to introduce the additional materials through Dr. Plunkett, she must properly supplement Dr. Plunkett's report under Rule 26(e)(2), and Boehringer shall have an opportunity to depose Dr. Plunkett regarding the impact of the additional documents on her opinions.

16. Expert Opinions of Dr. Brian Harvey (ECF No. 75)

Denied.

II. Plaintiff's Omnibus Motion in Limine (ECF No. 58)

1. Good Company Evidence

Deferred to trial.

2. "FDA Label"

Deferred to trial.

3. FDA Titration Determination

Deferred to trial.

4. Tort Reform

Deferred to trial.

5. "Beasley" Article

Deferred to trial. Defendant shall be allowed to make a proffer in advance of trial to qualify the Beasley article as a learned treatise for the purpose of establishing a hearsay exception.

It is hereby ORDERED that the foregoing, including the attachments thereto, constitutes the pretrial order in the above case and supersedes the pleadings which may not be further amended except by order of the court to prevent manifest injustice.

This 6th day of November, 2018.

_S/Clay D. Land
CLAY D. LAND
United States District Court Judge
Middle District of Georgia

Exhibit A
All material undisputed facts established by the
pleadings, depositions, or admissions of the parties

The parties have not agreed to any material undisputed facts.

Exhibit B
Depositions that each party intends to introduce at trial

1. Plaintiffs

Plaintiff may present the following witnesses at trial by means of deposition:

- Shane Darrah, M.D.
- William Fortson, M.D.
- Cameron Kersey, M.D.
- Michael Sims, M.D.
- Andreas Barner, M.D.
- Martina Brueckmann, M.D.
- Christopher Corsico, M.D.
- Klaus Dugi, M.D.
- Siegfried Eberle, M.D.
- Jeffrey Friedman, M.D.
- Michelle Kliewer
- Paul Reilly, M.D.
- Joanne Van Ryn, Ph.D.

Page/line designations for each deposition are attached hereto in the order the witnesses names appear above.

2. By BI

BI may present the following witnesses at trial by means of deposition (as necessary in light of Plaintiff's final designations):

- Virginia Chambers
- Shane Darrah, M.D.
- Michael Sims, M.D.
- William Fortson, M.D.
- Cameron Kersey, M.D.
- Andres Barner, M.D.
- Martina Brueckmann, M.D.
- Robert Buchberger, M.D.
- Christopher Corsico, M.D.
- Klaus Dugi, M.D.
- Siegfried Eberle, M.D.
- Jeffrey Friedman, M.D.
- Jörg Kreuzer, M.D.
- Lisa Matzen, Ph.D.
- Michelle Kliewer
- Paul Reilly, M.D.

- Joanne Van Ryn, Ph.D.

Page/line designations for each deposition are attached hereto in the order the witnesses names appear above.

Exhibit C
All exhibits that each party intends to tender into evidence at trial

Pursuant to the Court's July 26, 2018 Order [Doc. 76], the parties have exchanged deposition designations, counter-designations, and objections (including to exhibits contained in such deposition designations), and have met and conferred with regard to such designations and objections. The parties have further agreed to narrow the scope of such deposition designations pursuant to the following schedule: Plaintiff to provide her narrowed designations to Defendant by November 9, 2018; Defendant to provide Plaintiff with its objections and counter-designations by November 16, 2018, the parties to meet-and-confer thereafter and provide to the Court any outstanding objections by November 28, 2018.

For trial exhibits, the parties have stipulated that the party presenting a witness will provide via email to the opposing party the proposed direct examination exhibits the party intends to use on a given day of trial by 7:00 pm the prior evening, and the opposing party will provide via email any objections to those exhibits by 7:00 am the following morning.

Plaintiffs' full exhibit list is attached hereto as Attachment 1.

BI's exhibit list is attached hereto as Attachment 2.

Exhibit D
Form of all possible verdicts to be considered by the jury

1. Plaintiff[7]

Question 1:

A. We the jury find for the Plaintiff in the amount of $_____

OR

B. _____ We the jury find for the Defendant.

Question 2:

If you find for the Plaintiff, are punitive damages against the Defendant appropriate?

_____ Yes _____ No

Question 3:

We the jury award punitive damages against the Defendant in the amount of

$_____.

[7] Plaintiff reserves the right to amend, modify, or supplement this proposed form as necessary.

II. Defendant[8]

a. Liability Phase

According to the principles of law as instructed by the Court and the facts as you find them, please answer the following:

Part I – Warning/Label

1. Did Plaintiff prove by a preponderance of the evidence that BI failed to provide an adequate warning of the risks associated with the use of Pradaxa?

Yes _____

No _____

If your answer is "No," please have your foreperson sign and date the verdict form. If your answer is "Yes," go to Question 2.

2. Did Plaintiff prove by a preponderance of the evidence that Mr. Chambers' prescribing doctor would not have prescribed Pradaxa to him if an adequate warning had been given?

Yes _____

No _____

If your answer is "No," please have your foreperson sign and date the verdict form. If your answer is "Yes," go to Question 3.

3. Did Plaintiff prove by a preponderance of the evidence that Pradaxa caused Mr. Chambers' death?

[8] Defendant Boehringer Ingelheim respectfully submits its proposed verdict forms, without waiving any of its defenses or arguments, and without conceding that there is a fact issue on any question pertaining to liability or damages. Defendant reserves the right to amend, modify, or supplement this proposed form as necessary. Specifically, BI reserves the right to supplement this form, should the Court determine that additional claims will be tried to the jury. Further, BI reserves its right to seek a directed verdict after the close of Plaintiff's case in chief and to seek any additional appropriate relief during or after trial.

Yes _____

No _____

If your answer is "No," please have your foreperson sign and date the verdict form. If your answer is "Yes," go to Part II.

Part II – Damages

4. What sum of money, if any, do you find, by a preponderance of the evidence, to be the total amount of Plaintiff's damages caused by Defendant's failure to provide an adequate warning of the risks associated with Pradaxa?

$ _____

Part III – Punitive Damages

5. Did Plaintiff prove, by clear and convincing evidence, that BI acted with willful misconduct, malice, fraud, wantonness, oppression, or an entire want of care raising the presumption of conscious indifference to consequences?

Yes _____

No _____

If your answer is "No," have your foreperson sign and date the verdict form. If your answer is "Yes," go to Question 6.

6. Has Plaintiff proven, by clear and convincing evidence, that punitive damages are necessary to punish BI and to deter similar conduct by them in the future?

Yes _____

No _____

Have your foreperson sign and date the verdict form.

SO SAY WE ALL.

_____ _____

Date Foreperson's Signature

b. Punitive Damages Phase[9]

What amount of punitive damages, if any, do you assess?

$ _____

Have your foreperson sign and date the verdict form.

SO SAY WE ALL.

_____ _____

Date Foreperson's Signature

[9] BI submits this punitive damages verdict form for use in the event that the jury finds, in the liability phase of the trial, that punitive damages are appropriate.