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

In a Memorandum Opinion and Order issued on May 31, 2018, this Court dispensed with a majority of the pending motions in this matter, including the parties' cross-motions for summary judgment and related motions *in limine*. *Mem. Op. and Order*, ECF No. 118. However, five motions still remain unresolved: (1) Defendant's Omnibus Motion to Exclude the Opinions of Plaintiff's General Experts ("Defendant's Omnibus Motion") (ECF No. 47); (2) Defendant's Motion *in Limine* No. 2 to Exclude Evidence, Testimony, and Argument on Financial Metrics ("Financial Metrics Motion") (ECF No. 64); (3) Plaintiffs' Omnibus Motion *in Limine* ("Plaintiffs' Omnibus Motion") (ECF No. 73); (4) Defendant's Motion *in Limine* No. 1 to Exclude Evidence, Testimony, and Argument Regarding Alleged Spoliation Issues, MDL Discovery Sanctions, and other Litigation ("Motion to Exclude Spoliation") (ECF No. 63); and (5) Plaintiffs' Motion for Spoliation Finding and Adverse Inference Charge ("Motion for Sanctions") (ECF No. 71). After

holding a hearing on June 5, 2018, during which parties offered argument regarding each of those five remaining motions, the Court is prepared to rule.

Accordingly, and as explained below, the Court **GRANTS, IN PART** and **DENIES**, **IN PART**, Defendant's Omnibus Motion (ECF No. 47), **DENIES** Defendant's Financial Metrics Motion, **GRANTS**, **IN PART** and **DENIES**, **IN PART**, Plaintiffs' Omnibus Motion (ECF No. 73), **GRANTS**, **IN PART** and **DENIES**, **IN PART**, Defendant's Motion to Exclude Spoliation (ECF No. 63), and **DENIES** Plaintiffs' Motion for Sanctions (ECF No. 71).

For the factual background of this matter, refer to the Court's Memorandum Opinion and Order that was issued on May 31, 2018. *See Knight v. Boehringer Ingelheim Pharms., Inc.*, No. 3:15-cv-6424, 2018 WL 2470990, at *1-6 (S.D.W. Va. May 31, 2018) (Chambers, J.). Due to that lengthy recitation of this case's facts, the Court will not repeat that information here.

I. STANDARD OF REVIEW

A. 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) (italics original) (quoting *Oglesby v. Gen. Motors Corp*., 190 F.3d 244, 250 (4th Cir. 1999)). While using reliable or valid methods, the expert must also rely upon the facts and data of the type that "experts in the particular field would reasonably rely" upon. Fed. R. Evid. 703. For instance, an expert may rely upon the work of other individuals in his or her field, as well as the testimony of a lay witness. *See Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 789 (7th Cir. 2017) ("Of course, as a general matter, there is nothing objectionable about an expert relying upon the work of a colleague."); *U.S. v. Mann*, 712 F.2d 941, 942 (4th Cir. 1983) (rejecting a challenge to the admissibility of an expert's opinion where the expert relied upon another witness's testimony). However, as Rule 703 reflects, the determination regarding what constitutes acceptable information to rely upon is context-dependent, and specific to the field of the expert. Fed. R. Evid. 703 advisory committee's note (noting that, for example, a physician can rely upon a "considerable variety" of information from "numerous sources").

"[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).

B. Adverse Instruction Standard Under Rule 37(e)

Central to the integrity of the judicial process, our adversarial system relies upon the presentation of evidence to separate the wheat from the chaff, and to reveal the truth of the matter. *See Silvestri v. General Motors Corp.*, 271 F.3d 583, 590 (4th Cir. 2001). Tampering with the completeness of the necessary evidence may require court action to ensure judicial integrity. *See id.* Spoliation refers to this inference with evidentiary soundness, defined as "the destruction or material alteration of evidence or [ ] the failure to preserve property for another's use as evidence in pending or reasonably foreseeable litigation." *Id.* (citing *West v. Goodyear Tire & Rubber Co.*, 167 F.3d 776, 779 (2d Cir. 1999)). A federal court's power to impose sanctions for spoliation arises both from "(1) [Federal Rule of Civil Procedure] 37(e), and (2) its inherent power . . . to redress conduct which abuses the judicial process." *Steves & Sons, Inc. v. JELD-WEN, Inc.*, No. 3:16-cv-545, 2018 WL 2023128, at *3 (E.D. Va. May 1, 2018) (internal quotation marks omitted) (quoting *Silvestri*, 271 F.3d at 590). Courts have broad discretion when determining whether or not to impose sanctions regardless of the source of the court's power to do so. *Id.* (citing *Turner v. United States*, 736 F.3d 274, 281 (4th Cir. 2013)).

Rule 37(e) governs a court's spoliation analysis concerning electronically stored information ("ESI"). Amended effective December 1, 2015, the relatively new formulation of the rule provides in whole:

> If electronically stored information that should have been preserved in the anticipation or conduct of litigation is lost because a party failed to take reasonable steps to preserve it, and it cannot be restored or replaced through additional discovery, the court:
>
> (1) upon finding prejudice to another party from loss of the information, may order measures no greater than necessary to cure the prejudice; or
>
> (2) only upon finding that the party acted with the intent to deprive another party of the information's use in the litigation may:
>
> (A) presume that the lost information was unfavorable to the party;
>
> (B) instruct the jury that it may or must presume the information was unfavorable to the party; or
>
> (C) dismiss the action or enter a default judgment.

Fed. R. Civ. P. 37(e)[1]. As laid out by the rule, a movant must establish four threshold elements before a court may consider the appropriateness of sanctions. Those four elements are: "(1) the information should have been preserved, (2) the information was lost, (3) the loss occurred because a party failed to take reasonable steps to preserve it, and (4) the information cannot be restored or recovered through additional discovery." *In re Ethicon, Inc.*, No. 2:12-cv-497, 2016 WL 5869448, at *3 (S.D.W. Va. Oct. 6, 2016) (Goodwin, J.).

[1] This amended formulation of Rule 37(e) "applies to all civil matters commenced after December 1, 2015, and to all proceedings pending on that date, unless its application 'would be infeasible or work an injustice.'" *Jenkins v. Woody*, No. 3:15cv355, 2017 WL 362475, at *13 (E.D. Va. Jan. 21, 2017) (quoting Fed. R. Civ. P. 86). The Court finds that the application of the amended version of the rule neither is infeasible, nor will work an injustice. Additionally, in both their briefing and their argument during the June 5th hearing, the parties relied upon the currently effective version of Rule 37(e). *See Pls.' Reply in Supp. of Mot. for Sanctions*, ECF No. 104, at 2; *Def.'s Resp. to Mot. for Sanctions*, ECF No. 85, at 7-9 & n.3.

After establishing the four-part threshold, a court must then consider whether the movant has established one of two options that would permit imposing sanctions. The first, under Rule 37(e)(1), the Court may impose a proportional sanction upon the finding of prejudice. *Id.* Rule 37(e)(2), the second option, requires a finding that a "party acted with the intent to deprive the opposing party of relevant information." Fed. R. Civ. P. 37(e)(2). If, and only if, a court makes that required finding of intent to deprive, then a court may impose one of the three more severe sanctions, which includes an adverse instruction. *In re Ethicon, Inc.*, 2016 WL 5869448, at *3.

Although Rule 37(e) clearly announces the required showings, that of prejudice or intent to deprive, determining whether a scenario meets those standards lacks certitude. Generally, courts find prejudice when spoliation compromises a party's ability to present its case. *See Victor Stanley, Inc. v. Creative Pipe, Inc.*, 269 F.R.D. 497, 532 (D. Md. 2010) (citing *Silvestri*, 271 F.3d at 593-94). Phased differently, prejudice arises when a party "cannot present evidence essential to its underlying claim." *Id.* (internal quotation marks omitted) (quoting *Krumwiede v. Brighton Assocs., L.L.C.*, No. 05 C 3003, 2006 WL 1308629, at *10 (N.D. Ill. May 8, 2006)). But lacking a rigid definition, prejudice "range[s] along a continuum from an inability to prove claims or defenses to little or no impact on the presentation of proof." *Id.* (internal quotation marks omitted) (quoting *Rimkus Consulting Gp., Inc. v. Cammarata*, 688 F.Supp.2d 598, 613 (S.D. Tex. 2010)). Regardless of the malleable standard for prejudice, determining whether prejudice exists given a set of facts "necessarily [requires] an evaluation of the information's importance in the litigation." Fed. R. Civ. P. 37, Comm. Notes on Rules—2015 Amendment.

For the finding of an intent to deprive, the Fourth Circuit has not provided guidance regarding the level of intent required. *Steves & Sons, Inc.*, 2018 WL 2023128, at *10 (citing *Jenkins*, 2017 WL 362475, at *17). However, the Rule 37(e) "intent" is a stringent requirement

that "does not parallel to other discovery standards." *Jenkins*, 2017 WL 362475, at *17 (citing *Buckley v. Mukasey*, 538 F.3d 306, 323 (4th Cir. 2008) and *Trigon Ins. Co. v. United States*, 204 F.R.D. 277, 287 (E.D. Va. 2001)).

Even assuming that a movant satisfies the burden, and a court makes one of the two prerequisite findings, a court is not required to impose sanctions. *BMG Rights Mgmt. (US) LLC v. Cox Commc'ns, Inc.*, 199 F.Supp.3d 958, 986 (E.D. Va. 2016), *rev'd, in part, on different grounds*, 881 F.3d 293 (4th Cir. 2018). Consistent with the purpose and goal for their imposition, sanctions reside in the broad discretion of the Court. *See Turner v. United States*, 736 F.3d 274, 281-82 (4th Cir. 2013).

II. DISCUSSION

Given that the pending motions touch upon differing topics, the Court will address each separately, with the exception of Defendant's Motion to Exclude Spoliation and Plaintiffs' Motion for Sanctions. The Court will address those two motions concerning spoliation and sanctions together because they intersect and largely overlap.

A. Defendant's Omnibus Motion

In its Omnibus Motion, Defendant moves to preclude certain opinions from several of Plaintiffs' experts. The opinions that Defendant seeks to exclude generally fall into three broad categories: (1) opinions regarding monitoring; (2) opinions regarding labeling sufficiency; and (3) opinions based upon Boehringer Ingelheim's ("BI") internal documents. *Def.'s Mem. in Supp. of Omnibus Mot.*, ECF No 48, at 1. As detailed below, the Court disagrees with Defendant's argument for preclusion for each category, with one relatively minor exception. Therefore, the Court **GRANTS, IN PART**, and **DENIES, IN PART** Defendant's Omnibus Motion.

a. Monitoring Opinions

Plaintiffs have multiple experts who have opined regarding the relative need or appropriateness of recommending a monitoring regime for patients taking Pradaxa who have a heightened risk of experiencing a major bleed. *Pls.' Resp. to Def.'s Omnibus Mot.*, ECF No. 52, at 11-15. Plaintiffs have three experts that opine generally regarding monitoring, Drs. Baruch, Plunkett, and Chertow. *Def.'s Mem. in Supp. of Omnibus Mot.*, at 3. In Dr. Baruch's opinion, he "explains how the decreasing stroke-prevention benefit at high Pradaxa levels means that there exists a level of Pradaxa beyond which there is no clinical benefit." *Pls.' Resp. to Def.'s Omnibus Mot.*, at 12. And based upon that, Dr. Baruch opines that BI should have instructed doctors to monitor Pradaxa levels. *Id.* at 13. Similarly, Dr. Plunkett opines that BI should have provided doctors with information regarding both a target range for Pradaxa levels, and a monitoring regime for ensuring that a patient's levels reside within that range. *Id.* at 13; *Def.'s Mem. in Supp. of Omnibus Mot.*, at 9. Finally, Dr. Chertow explains both "kidney function generally and . . . how kidney function affects the absorption of [Pradaxa], plasma concentrations of the anticoagulant[,] and the corresponding effects on patients." *Ex. 18 to Pls.' Resp. to Def.'s Omnibus Mot.*, ECF No. 52-18, at 3. Like the other two doctors, Dr. Chertow ultimately opines that based upon his knowledge and experience, BI should have established a therapeutic range, and it should have recommended that doctors monitor. *Def.'s Mem. in Supp. of Omnibus Mot.*, at 11; *Pls.' Resp. to Def.'s Omnibus Mot.*, at 15-16.

Defendant poses two types of challenges to the monitoring opinions. First, as a broad objection, Defendant argues that the monitoring opinions, as a whole, do not "fit the facts of this case." *Def.'s Mem. in Supp. of Omnibus Mot.*, at 3. Second, Defendant challenges the opinions of each of those doctors, for slightly different reasons, but all of the challenges revolve around the "unreliability" of the doctors' opinions.

Taking first the issue of fit, it is axiomatic that "expert testimony which does not relate to any issue in the case is not relevant [and] non-helpful." *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *2 (S.D.W. Va. July 8, 2014) (quoting *Daubert*, 509 U.S. at 591-92). Defendant claims that the opinions of Drs. Baruch, Plunkett, and Chertow "are not relevant to this case because there is no evidence that a monitoring instruction would have impacted Ms. Knight's treatment." *Def.'s Mem. in Supp. of Omnibus Mot.*, at 3. Without this evidence, Defendant lacks a "case specific connection." *Id.* at 4. In essence then, Defendant appears to argue that because the monitoring opinions of the three doctors do not address Ms. Knight's scenario specifically, their opinions are irrelevant. But Defendant misapprehends both Plaintiffs' evidentiary production to this point, and Plaintiffs' ability to retain multiple experts to connect broader topics to the specifics of Ms. Knight's case.

As this Court as already determined in its previously issued Memorandum Opinion and Order, Plaintiffs have sufficiently adduced evidence demonstrating a causative link between the lack of a warning to monitor and Ms. Knight's ultimate injuries to establish a question of fact. *See Knight*, 2018 WL 2470990, at *14, *16-17. That judicial finding reflects the necessary showing of a causal relationship.

However, during argument, when confronted with this Court's previous finding, counsel for Defendant attempted to downplay its importance. Without legal citation, Defendant's counsel contended that the standard necessary to satisfy case-specific causation for the purposes of summary judgment differs from the connection required to make an expert opinion relevant under *Daubert*. Oddly, despite this contention during the hearing, in its brief, Defendant cites *Meade v. Parsley*, No. 2:09-cv-00388, 2010 WL 4909435 (S.D.W. Va. Nov. 24, 2010), to support its argument that the doctors' monitoring opinions are irrelevant. *Def.'s Mem. in Supp. of Omnibus*

Mot., at 3-4 (citing *Meade*, 2010 WL 4909435, at *5, 9). In *Meade*, Judge Copenhaver had before him a motion for summary judgment on various product liability claims. Indeed, Judge Copenhaver's causation analysis, on which Defendant relies in arguing for the preclusion of the three doctors' opinions, was in the context of summary judgment. Therefore, Defendant's leaky pail of argument holds no water. The Court's earlier finding establishes the relevance of the monitoring opinions to this case, as well as the connection between them and Ms. Knight's specific case.

In addition to challenging the connection between the monitoring opinions and the facts of this case, Defendant also advocates for a requirement that the opinions of Plaintiffs' experts must address every aspect of the case. In other words, Defendant seems to argue that each doctor must provide not only information regarding a general connection between Pradaxa and the need to monitor, but also that each doctor must connect that general principle to Ms. Knight.

In doing so, Defendant fails to recognize that Plaintiffs may, as they have done, use multiple experts to assemble the logical links needed to demonstrate both the insufficiency of Pradaxa's warnings and what that insufficiency caused in Ms. Knight's case. *See Zellers v. NexTech Ne., LLC*, 533 Fed.Appx. 192, 197 (4th Cir. July 17, 2013) (per curiam) ("[T]here is no prohibition on utilizing multiple experts to establish various components of a party's case . . . ."). Plaintiffs' experts demonstrate mastery in distinct areas, such as kidney function for Dr. Chertow, clinical experience for Dr. Baruch, and pharmacology for Dr. Plunkett. And in opining within their areas of expertise, the doctors' opinions, together, weave a tapestry of connections. By offering these opinions, together with the opinion of Dr. Ashhab, Plaintiffs' case-specific expert, and the testimony of Ms. Knight's treating physicians, Plaintiffs bridged the gap between the general

causative elements and what allegedly occurred in this case. *See Knight*, 2018 WL 2470990, at *14, *16-17.

A single expert's opinion cannot be analyzed in a vacuum, devoid of the meaningful context of issues presented and a party's other evidence and experts. *See In re Ethicon, Inc.*, MDL No. 2327, 2017 WL 6346633, at *3 (S.D.W. Va. Dec. 12, 2017) (Chambers, J.) ("A single expert need not provide all the pieces of the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case." (citing *Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 691, 710 (S.D.W. Va. 2014))). Nor does an expert need be a jack-of-all-trades. In this case, Plaintiffs' showing satisfies the Court that the opinions of Drs. Baruch, Plunkett, and Chertow are relevant in this case. *See Daubert*, 509 U.S. at 592 (providing that "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility").

With the fitness addressed, the Court must also confront Defendant's argument for preclusion based upon the unreliability of the three doctors' opinions. As mentioned, Defendant's individual objections all boil down to a challenge of the reliability of the doctors' opinions. Briefly summarizing, Defendant argues Dr. Baruch does not understand the modeling on which he based his opinion, submits "subjective" monitoring opinions, and has expressed views that are contradictory to his opinions in this case, and his opinions fail "every *Daubert* factor for reliability." *Def.'s Mem. in Supp. of Omnibus Mot.*, at 5-8. With regard to Dr. Plunket, Defendant contends that her opinions are unreliable because her opinions were "inherently contradictory" and "arbitrary," and because Dr. Plunkett never tested, published, or subjected to peer review, her monitoring opinion. *Id.* 9-10. Lastly, Defendant argues that the Court should preclude the monitoring opinions of Dr. Chertow because he failed to identify a specific therapeutic range for monitoring, and had neither derived, nor published, a way to obtain a specific therapeutic range.

Id. 11-12. Contrary to Defendant's contentions, the Court finds each of the doctors' opinions to be sufficiently reliable, and based upon information that experts of their kind would rely upon.

Not only did Dr. Baruch offer a thorough, amply supported opinion, but he also relied, in large part, upon information, studies, and models published by Defendant and its researchers. *Ex. 16 to Pls.' Resp. to Def.'s Omnibus Mot.*, ECF No. 52-16, at 17, 26-35, 48-55, 58-76. Specifically, Dr. Baruch relied upon data and information provided by the RE-LY, RE-ALIGN, and DIVERSITY trials, all of which were conducted by Defendant. *Id.* at 58-76. Not only did Dr. Baruch rely upon the results of these trials, but he was also one of the researchers collaborating on the RE-LY trial. *Id.* at 15. In determining that Defendant should have designated a therapeutic range, Dr. Baruch looked at *BI's own data*, as well as various other peer-reviewed studies. This is the exact type of information the Fourth Circuit has encouraged experts to use. *See Nease*, 848 F.3d at 231 ("One especially important factor for guiding a court in its reliability determination is whether a given theory has been tested.").

In light of Dr. Baruch's reliance upon peer-reviewed, clinical trials and medical literature, in addition to his own clinical experience, Defendant's argument that Dr. Baruch's opinion should be excluded because he did not understand the pharmacokinetic modeling falls short. *See Def.'s Mem. in Supp. Omnibus Mot.*, at 5. Although Dr. Baruch may not have fully understood the intricacies of pharmacokinetics, that does not detract from the reliability of his opinion. Dr. Baruch does not need to be able to explain in detail every part of the complicated multi-disciplinary input involved in pharmaceutical development in order to reliably interpret data from clinical trials, peer-reviewed medical literature, and BI's internal documents. Indeed, in reaching his conclusions, Dr. Baruch permissibly relied upon the type of information that an expert in his field of medicine

would reasonably rely upon. *See Mann*, 712 F.2d at 942 (rejecting a challenge to the admissibility of an expert's opinion where the expert relied upon another witness's testimony).

Similarly, Defendant's other challenges to Dr. Baruch's monitoring opinions are to no avail. Defendant points to Dr. Baruch's inability to cite to "'any clear rules' regarding which patients should have their dose adjusted based upon a single test," as well as Dr. Baruch's previous, and seemingly contradictory statements. *See Def.'s Mem. in Supp. of Omnibus Mot.*, at 6-8. But these objections do not indicate that Dr. Baruch's monitoring opinions are unreliable. That Dr. Baruch could not identify an exact therapeutic range for all patients does not detract from his opinion. Dr. Baruch opined that BI should have instructed doctors and patients that taking Pradaxa as recommended can result in dangerous concentrations of the drug, and that they should monitor those concentration levels in order to act accordingly to minimize risk. Stating that a manufacturer should provide a safe range for medication, or at the very least identify a level at which a medication's blood concentration presents a greater increase in risk than benefit, does not require the establishment of a single therapeutic range applicable to every and all patients. As demonstrated by BI's own documents, upon which Dr. Baruch partly relied, certain concentrations of Pradaxa offered little by way of increased stroke prevention, but did meaningfully increase the risk of a major bleed. Dr. Baruch did not need to provide "any clear rules" about which patients' doses should be adjusted. Instead, he only needed to identify the severity of the known risk of higher Pradaxa concentrations, explain the occurrence of those higher concentrations, and opine has to how to mitigate those risks through monitoring, all of which was based upon a review of the relevant medical research and his experience. Indeed, Dr. Baruch did just that.

Additionally, to the extent that Dr. Baruch made seemingly contradictory statements during his deposition or in previous publications, those statements would go to Dr. Baruch's credibility.

Wise v. C.R. Bard, Inc., No. 2:12-cv-1378, 2015 WL 521202, at *11 (S.D.W. Va. Feb. 7, 2015) (Goodwin, J.) ("Furthermore, listening to testimony and deciding whether it is contradictory is the quintessential jury function of determining credibility of witnesses." (internal quotation marks omitted) (citing *Crowley v. Chait*, 322 F.Supp.2d 530, 553-54 (D.N.J. 2004))). That credibility issue, with the benefit of thorough cross-examination, will not prevent the admissibility of Dr. Baruch's opinion. *See id.*; *Bresler v. Wilmington Tr. Co.*, 855 F.3d 178, 195-96 (4th Cir. 2017) (finding that challenges that "affect the weight and credibility" of an expert's opinion do not affect admissibility).

Turning to the opinions of Drs. Plunkett and Chertow, Defendant contends that their monitoring opinions are unreliable because, in essence, neither doctor would identify a single therapeutic range for Pradaxa. *Def.'s Mem. in Supp. of Omnibus Mot.*, at 9-11. Dr. Plunkett agreed that a wide range of Pradaxa plasma concentrations could have therapeutic benefit to patients. Dr. Chertow refused to identify a single concentration therapeutic range. However, neither of these issues, recognizing a potentially large range of concentrations that could provide medical benefit and not identifying one specific range for therapeutic concentration, impinges upon the reliability of the doctors' opinions. Instead, Plaintiffs have elicited the opinions of Drs. Plunkett and Chertow regarding whether BI should have identified *some* scientifically supported range, and should have indicated that concentrations of Pradaxa could become dangerous, even for those who took it as prescribed. *Pls.' Resp. to Def.'s Omnibus Mot.*, at 14-16.

Further, the two doctors offer unique perspectives on the need for BI to have identified some range. Dr. Plunkett, with her background in toxicology, pharmacology, and FDA regulatory work, explains how Pradaxa's pharmacokinetic profile makes it "not possible to reliability predict blood levels that will be achieved for individual patients." *Ex. 21 to Pls.' Resp. to Omnibus Mot.*,

ECF No. 55-22, at 3-4, 7. In light of that variability analysis, Dr. Plunkett concludes that BI should have instructed doctors on a monitoring regime. *Id.* at 8-10. Dr. Chertow, on the other hand, approaches this case as a Board-Certified Nephrologist. He explains how kidney function greatly affects the absorption of Pradaxa. Based upon that variability, BI should have recommended monitoring to ensure that patients "are not excessively anticoagulated." These two doctors provide important and differing bases to explain the need to identify some therapeutic range, recommend the monitoring of Pradaxa concentrations in individuals with that therapeutic range in mind, and designate a method to test the Pradaxa concentrations reliably.

So too, that the doctors have neither run trials that have led to this opinion, nor previously published this opinion, does not affect their reliability under *Daubert*. They both relied upon their extensive medical knowledge and expertise, as well as the clinical trial data and BI's internal documents to arrive at their conclusions. *Ex. 18 to Pls.' Resp. to Omnibus Mot.*, at 5; *Ex. 21 to Pls.' Resp. to Omnibus Mot.*, at 5-6. Clinical trials, medical literature, as well as the internal medical research documents of BI, are the type of information that an expert of their kind would rely upon. Therefore, their lack of published material regarding their specific opinions in this case will not preclude admissibility. *See U.S. v. Thompson*, 232 F.3d 892, at *2 (4th Cir. Nov. 2, 2000) (unpub.) ("The district court did not abuse its discretion by permitting the expert to testify as to the basis of his opinion, as this was the type of information an [expert of that kind] would rely upon in order to arrive at an opinion." (citing Fed. R. Evid. 703 and *United States v. Corey*, 207 F.3d 84, 87-91 (1st Cir. 2000))).

b. Labeling Opinions

Defendant also challenges Plaintiffs' three experts who have opined regarding the insufficiency of BI's Pradaxa labeling. In addition to the labeling opinions of Drs. Baruch and

Chertow, Plaintiffs also offer the labeling opinion of Mr. Robert Gosselin. Addressing each of Defendant's challenges to these labeling opinions, in turn, the Court rejects its challenges, and will permit Plaintiffs to offer the labeling opinions.

Defendant argues, first, that Dr. Baruch's labeling opinion should be excluded because he both lacks the necessary qualification and uses unreliable methodology. *Def.'s Mem. in Supp. of Omnibus Mot.*, at 12-14. According to Defendant, Dr. Baruch is unqualified to offer a labeling opinion because he "is not an expert on the FDA generally or pharmaceutical labeling specifically." *Id.* at 12 (internal quotation marks and citation omitted). In support of this proposition, Defendant cites to Judge Goodwin's opinion in *In re Ethicon, Inc.*, No. 2:12-MD-2327, 2016 WL 4536885 (S.D.W. Va. Aug. 30, 2016) (Goodwin, J.). In doing so, Defendant argues that Dr. Baruch needs some sort of regulatory experience to opine as to the sufficiency of the warnings provided by BI, given the risks of Pradaxa. *Def.'s Mem. in Supp. of Omnibus Mot.*, at 12-13.

The Court does not read Judge Goodwin's opinion to support Defendant's argument. Citing his opinion in *Wise v. C.R. Bard, Inc.*, Judge Goodwin determined that the doctor in question in *In re Ethicon, Inc.* did not possess the additional expertise necessary to opine regarding what a label should contain. *In re Ethicon, Inc.*, 2016 WL 4536885, at *2. However, the citation to *Wise* illustrates the important background upon which Judge Goodwin excluded the doctor's label opinion in *In re Ethicon, Inc.* In *Wise v. C.R. Bard, Inc.*, Judge Goodwin found that a doctor possessed the necessary expertise to "evaluate Bard's warnings based on his knowledge of and experience with the risks of the [medical device]." 2015 WL 521202, at *14. Judge Goodwin, however, did exclude that same doctor from "opin[ing] on FDA regulations and whether a product label satisfies those regulations," without additional FDA or labeling expertise. *Id.* at *5, *14.

Therefore, when read in the full context, *In re Ethicon, Inc.* fails to support Defendant's argument. Instead, it bolsters Plaintiffs' position that Dr. Baruch may opine regarding the sufficiency of the label to notify doctors and patients of Pradaxa's risk. Like the doctors in *In re Ethicon, Inc.* and *Wise*, Dr. Baruch would not be permitted to opine regarding FDA regulations. But Dr. Baruch, with his ample clinical and research experience with anticoagulants, possesses the necessary qualifications to opine regarding the sufficiency of the label's warning to doctors and patients about Pradaxa's risks. *See Wise*, 2015 WL 521202, at *5, *14.

Defendant's objection regarding Dr. Baruch's methodology also lacks merit. Defendant argues that Dr. Baruch's opinion is unreliable because he "could not provide more than 'starting labeling language'" and because he did not know Europe's differing labeling standards even though he used Pradaxa's European label to help form his opinion. *Def.'s Mem. in Supp. of Omnibus Mot.*, 13-14. Oddly, both of these objections seem to suggest that Dr. Baruch *must* have a background in, and form opinions regarding, regulatory labeling requirements. However, as noted in the discussion of *In re Ethicon, Inc.* and *Wise*, that is not the case. Dr. Baruch is opining regarding Pradaxa's risks and whether the label sufficiently warned of those risks. He is not opining as to the regulatory standards. Therefore, as with Defendant's other objection to Dr. Baruch's labeling opinion, the Court disagrees.

Again contesting the opinion of Dr. Chertow, Defendant claims he, too, is unqualified and uses an unreliable methodology. Defendant's critique of Dr. Chertow mimics its objections to the opinions of Dr. Baruch: (1) he is not an FDA regulatory expert; and (2) he did not review the FDA regulations regarding labeling development. *Def.'s Mem. in Supp. of Omnibus Mot.*, at 15-16. However, for the same reasons it dismissed these concerns with Dr. Baruch, the Court again rejects

Defendant's unreliable methodology argument for Dr. Chertow's labeling opinion. *See supra* pp. 14-16.

With its last labeling opinion challenge, Defendant objects to the opinions of Mr. Robert Gosselin. Although not a medical doctor, Mr. Gosselin is a highly esteemed researcher in the field of anticoagulants. *See Ex. 19a to Pls.' Resp. to Omnibus Mot.*, ECF No. 52-19, at 4-6. In this case, Mr. Gosselin has opined regarding the efficacy of different blood concentration tests. *Ex. 19b to Pls.' Resp. to Omnibus Mot.*, ECF No. 52-20, at 12-18. Defendant argues, however, that Mr. Gosselin is unqualified to render any opinions related either to Pradaxa concentration testing or to any label information that would be relevant and helpful for that testing. In making that argument, Defendant focuses upon Mr. Gosselin's apparent lack of "regulatory expertise as well as the clinical perspective of a physician." *Def.'s Mem. in Supp. of Omnibus Mot.*, at 14-15.

Given Mr. Gosselin's extensive experience in the area of anticoagulant testing, the Court disagrees with Defendant's argument that he lacks the proper qualification. Not only is Mr. Gosselin the Chairperson for an international anticoagulant "guideline development committee for the International Council for Standardization in Haematology [sic]," but he is also a licensed clinical laboratory scientist with over 30 years of experience, publishing at least 20 peer-reviewed articles on laboratory testing of anticoagulants' effects, and consulting with physicians on matters of anticoagulation. *Ex. 19a to Pls.' Resp. to Omnibus Mot.*, at 4-6. Importantly, Mr. Gosselin has also presented at FDA sponsored workshops on anticoagulants, and participated in advisory meetings for multiple pharmaceutical companies, including BI. *Id.*at 4. Based upon Mr. Gosselin's extensive experience with various aspects of anticoagulant testing, the Court finds that he is sufficiently qualified to offer testimony regarding the anticoagulant testing for Pradaxa, as well as sufficiency of the testing and information provided by Defendant to doctors or patients.

c. Opinions Based Upon Company Documents

Defendant's final challenge in its Omnibus Motion pertains to the opinions of two of Plaintiffs' experts that were based upon BI's own documents. Defendant claims that the opinions of Drs. Plunkett and Baruch that were based upon BI's own documents should be excluded. Defendant argues that both of the opinions inappropriately attempt to explain Defendant's knowledge and motive, and that they were based upon a "cherry-picking" of documents. The Court agrees with aspects of Defendant's challenges regarding the expert testimony going to intent or motive. However, the Court does not agree with the reminder of Defendant's objections.

The Court believes that, given the nature of this case, the doctors' opinions regarding what BI knew and communicated to the FDA will provide helpful insight to the jury. *See Smith v. Pfizer*, 714 F.Supp.2d 845, 857 (M.D. Tenn. 2010) (allowing an expert to testify regarding his interpretations of internal documents); *but see In re Ethicon, Inc.*, No. 2:12-MD-2327, 2014 WL 186872, at *6 (S.D.W. Va. Jan. 15, 2014) (Goodwin, J.) (citing *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 547 (S.D.N.Y. 2004) and *In re Fosamax Prods. Liab. Litig.*, 645 F.Supp.2d 164, 192 (S.D.N.Y 2009)). An experts' deciphering of the complicated internal documents of a sophisticated pharmaceutical company will assist the jury in determining the relevant issues in this case. So too, both Dr. Plunkett, with her extensive background in regulatory affairs, and Dr. Baurch, with his ample experience in clinical use of anticoagulants, possess specialized knowledge and skills that qualify them to speak this issue.

The Court, however, will not permit Dr. Plunkett and Dr. Baruch to make, and opine about, the inferences of motive and intent. The jury, not an expert, should make those inferential leaps. *See, e.g.*, *Smith*, 714 F.Supp.2d at 857 (not allowing an expert to testify regarding intent or motive of the defendant)*; Talley v. Novartis Pharms. Corp.*, No. 3:08-cv-00361-GCM, 2011 WL 7941938,

at *1 (W.D.N.C. June 28, 2011) ("[C]ourts have held experts cannot testify about intent or motives because those opinions are to be formed by the jury." (citing *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 547, 554 (S.D.N.Y. 2004))).

Defendant also contends that the opinions of the two doctors should not be allowed because they are based upon cherry-picked documents. But Defendant's concern goes to the credibility and weight of their opinions, not admissibility. *See Chambers v. Boehringer Ingelheim Pharm., Inc.*, No. 4:15-CV-00068, 2018 WL 849081, at *6 (M.D. Ga. Jan. 2, 2018) ("Any unfamiliarity with the documents goes to the credibility of the experts' resulting opinions, not the admissibility."); *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2009 WL 3806436, at *11 (M.D. Fla. July 20, 2009) ("[Defendant's] objection regarding the selection of documents that Dr. Plunkett examined goes to the weight of her testimony, not its admissibility."). Any "cherry-picking" of documents or an expert's unfamiliarity with relevant documents may provide effective fodder on cross-examination.

Having resolved Defendant's Omnibus Motion, the Court will address Defendant's Financial Metrics Motion.

B. Defendant's Financial Metrics Motion

Defendant moves to exclude any evidence or argument about "BI's financial information, including its net worth, sales data, spending and profits related to Pradaxa, Praxbind or any other pharmaceutical product manufactured by BI." *Def.'s Financial Metrics Mot.*, ECF No. 64, at 1. Defendant claims that any financial information regarding the company is irrelevant to liability or substantially more prejudicial than probative. *Id.* at 1-3. Such information, argues Defendant, is not relevant to whether Defendant adequately warned Ms. Knight of Pradaxa's risks. *Id.* at 1-2. To

the extent that financial information is relevant to the remaining issues, Defendant maintains that the prejudicial risk of that information substantially outweighs the probative value. *Id.* at 2-3.

Plaintiffs respond that Defendant's own internal documents made financial information relevant. Plaintiffs point to multiple internal BI documents that state that monitoring or testing of Pradaxa concentration would "result in a major competitive disadvantage." *Ex. 1 to Pls.' Resp. to Def.'s Financial Metrics Mot.*, ECF No. 83-1, at 3. Internal BI emails also reflect the same concern about losing ground to competitors' anticoagulants if BI recommended a monitoring regime. *Ex. 3 to Pls.'s Resp. to Def.'s Financial Metrics Mot.*, ECF No. 83-3, at 1. Plaintiffs' claim that even BI's own launch video for Pradaxa emphasizes the dangling carrot of massive profits in store for the company and its employees because of Pradaxa's release. *Pls.' Resp. to Def.'s Financial Metrics Mot.*, ECF No. 83, at 3-4. In addition to noting the relevance of financial information to BI's development of Pradaxa's warnings, Plaintiffs also contend that the financial metrics are pertinent to their punitive damages claim under West Virginia law. *Id.* at 6-7 (citing W. Va. P.J.I § 1500 Punitive Damages; *Garnes v. Fleming Landfill Inc.*, 413 S.E.2d 897 (W. Va. 1991)).

Overall, the Court agrees with Plaintiffs. By evidence of its own internal operating, Defendant has made relevant information regarding Pradaxa-related finances. And although the evidence may prejudice Defendant minimally, the probative value of permitting the jury to see BI's potential motivation for not recommending monitoring outweighs the threat of prejudice. Finally, because Plaintiffs' punitive damages claim has survived summary judgment, West Virginia law instructs that financial information affects the consideration of punitive damages. *See* Syl. pt. 10, *Bowyer v. Hi-Lad, Inc.*, 609 S.E.2d 895, 899 (W. Va. 2004) ("The financial position of the defendant is relevant."). Therefore, the Court **DENIES** Defendant's Financial Metrics Motion to the extent that Plaintiffs seek to offer evidence regarding any actual or perceived economic

benefit or disadvantages in Defendant's development and sale of Pradaxa. However, without obtaining leave, the Court will not permit Plaintiffs to simply offer evidence related to Defendant's profitability or financial condition unrelated to Pradaxa's. The Court anticipates that the parties will bifurcate the punitive damages claim. If that is the case, the Court will address the admissibility of general financial information at a later point.

Next, the Court analyzes Plaintiffs' only remaining, non-spoliation motion, their Omnibus Motion *in Limine*.

C. Plaintiffs' Omnibus Motion

In their motion, Plaintiffs request that the Court exclude three categories of evidence and argument : (1) BI's performance of "good acts," its "good reputation," or its status as a "good company;" (2) the use of the term "FDA label" to refer to Pradaxa's label that was introduced by BI and approved by the FDA; and (3) any FDA determination that dose adjustment would not be beneficial for Pradaxa patients. *Pls.' Omnibus Mot.*, ECF No. 73.

Plaintiffs' objection to "good company" evidence, and evidence in the similar ilk, is persuasive. The Court will not permit Defendant to adduce evidence or argument related to its own good, company-wide reputation, its unrelated "good" or charitable acts, or other corporate practices indicative of its social conscious that are unrelated to Pradaxa. However, the Court will allow Defendant to introduce and describe itself to the jury. In that context, Defendant may identify, and provide evidence regarding, efforts that it took to be responsible, conscientious, or "good" only related to the development and marketing of Pradaxa. Similarly, Defendant will be permitted to offer evidence to establish its intent to produce a safe product.

In Plaintiffs' second *in limine* challenge, they seek to prevent Defendant from referring to Pradaxa's label as the "FDA label." Plaintiffs contend that this moniker would mislead and confuse

the jury. *Pls.' Omnibus Mot.*, at 4-6. The responsibility for the adequacy of a pharmaceutical label belongs to the manufacturer, not the FDA. *See Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009) ("Wyeth suggests that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times."). Plaintiffs argue that by allowing Defendant or its counsel to refer to the label as the "FDA label" the jury would believe that the FDA has the ultimate responsibility for the label's sufficiency. *Pls.' Omnibus Mot.*, at 5. The Court, however, does not believe that this issue presents such a pressing matter as to be dealt with *in limine*.

The parties agree that the label was, as it must be, approved by the FDA. Therefore, the Court is not convinced that reference to the "FDA label," as opposed to the "FDA approved label," meaningfully increases the risk of confusion. But the Court will not foreclose Plaintiffs from raising specific objections upon the potential risk of a misleading reference during the trial. The determination of whether a particular reference to the label presents a significant risk of confusion is context-dependent. Therefore, Plaintiffs may raise specific objections at trial.

On Plaintiffs' last *in limine* issue, the Court agrees with Plaintiffs. Plaintiffs want to prevent Defendant from arguing that the FDA has affirmatively determined that dose adjustment of Pradaxa, based upon blood plasma concentrations, would not be beneficial for patients. And, relatedly, Plaintiffs preemptively argue that Defendant should not be permitted to contend that it shared its titration analysis with the FDA for its confirmation. *Pls.' Omnibus Mot.*, at 8. Although Plaintiffs concede that BI transmitted *data* to the FDA, they argue that BI never provided the agency with its own *analysis* of the data. *Id.*

In response to the motion, Defendant makes the exact assertion that Plaintiffs seek to exclude:

> Contrary to Plaintiffs' claims, BI has communicated extensively with the FDA regarding whether routine monitoring of Pradaxa plasma levels or dose adjustments guided by such monitoring might improve Pradaxa's benefit-risk profile. Based on these discussions, the FDA agreed with BI that there is no evidence to support routine monitoring or dose adjustment of Pradaxa, and has consistently approved Pradaxa on a fixed-dose basis without any requirement for monitoring plasma levels or adjusting dosage.

Def.'s Resp. to Pls.' Omnibus Mot., ECF No. 86, at 6 (footnote citation omitted). Supporting this statement, Defendant cites to a transcript of a September 2010 FDA Advisory Committee Meeting. *See id.* at n. 5. That committee meeting transcript is the only support Defendant cites for its claim that the FDA determined that dose adjustment was not necessary. However, a closer inspection of both the transcript itself, as well as the circumstances surrounding the meeting transcript, lead the Court to agree with Plaintiffs. Defendant will not be allowed to claim that the FDA has reached a determination, one way or another, regarding the appropriateness of dose adjustment.

As an initial matter, that September 2010 meeting occurred more than a month before the FDA even approved Pradaxa. *Pls.' Reply in Supp. of Omnibus Mot.*, ECF No. 105, at 8. So too, instead of constituting an official FDA action, the Advisory Committee Meeting merely involved a discussion between representatives for the industry, the FDA, and independent scientists. *Id.* In light of these two facts alone, the Court is not inclined to find that the discussion points constitute official FDA determinations. Otherwise, the FDA and other agencies would be forced to reckon with an abundance of "determinations" occurring in hotel conference rooms all across the country.

Even the meeting transcript itself indicates the non-binding, non-determinative nature of the Advisory Committee Meeting. In response to one doctor's explanation for why she or he believed monitoring was unnecessary, another doctor challenges the rationale:

> I think you've just made a very cogent argument *to monitor*. If you have a predictor for an individual subject, a dose has a wide variability, but within that subject a constant one, *why not monitor single time at steady state to make sure you have the dose right* in that one individual.

Ex. 1 to Def.'s Resp. to Omnibus Mot., ECF No. 86-1, at 5 (emphasis added). This conversational rebuttal demonstrates that the transcript does not contain the official and final conclusion of the FDA. Instead, it shows that the Advisory Committee Meeting was a discussion, a conversation, an exchange of informed beliefs. Although certainly a valuable exchange of information among rigorous medical researchers, the statements made during that meeting will not act as official, binding FDA decisions in this case.

Concerning BI's exchange of titration analysis, Plaintiffs claim that Defendant never shared its titration analysis with the FDA. In Plaintiffs' view, Defendant incorrectly attempts to characterize the exchange of *data* to be synonymous with the change of *analysis*. *Pls.' Omnibus Mot.*, at 8. Plaintiffs emphasize that Defendant's own employee, Michelle Kliewer, has confirmed that BI never provided the FDA with the titration analysis performed by one of its employees, Dr. Lehr. *See id.*; *Ex. 2 to Pls.' Omnibus Mot.*, ECF No. 73-2, at 5, 14. And according to Ms. Kliewer's testimony, "all the FDA submissions [go] through [her]." *Ex. 2 to Pls.' Omnibus Mot.*, at 15.

Defendant rebuts Plaintiffs' contention by citing five exchanges of information between it and the FDA. *Def.'s Resp. to Omnibus Mot.*, at 7-8. Through various emails and submissions to the FDA, it appears that Defendant did, at the very least, send some information to the FDA. In essence, Defendant uses these exchanges to establish that the FDA has been fully informed regarding its analyses, but has not imposed a monitoring requirement or dose adjustment. Plaintiffs reply that although Defendant may have sent some information, like EMA (European Medicines Agency) documents, "the FDA has never responded in any formal way" to those documents." *Pls.' Reply in Supp. of Omnibus Mot.*, at 10. Regardless of the parties' quibbling over the value of the

information that BI has sent to the FDA about its titration analysis, the Court believes the dates of the submitted information raise the biggest issue.

Each of the five exchanges occurred long after Ms. Knight had experienced her major bleed and passed away. The earliest information sited by Defendant was sent on July 24, 2014. *Def.'s Resp. to Omnibus Mot.*, at 7. This is nearly a year after Mrs. Knight passed away. Defendant then cites emails and submissions in August and December of 2014, August of 2015, and February of 2016. *Id.* at 8. Despite the dates of the apparent exchanges of information regarding titration analysis, Defendant contends that these exchanges support that the FDA has made a determination regarding the dose adjustment. *Id.* at 9. However, the only citation Defendant provides for the FDA's supposed action was the September 2010 Advisory Meeting transcript. Aside from this Court's determination that the transcript does not reflect an official determination of the FDA, Defendant cannot contend that the FDA considered supposed titration analysis that BI sent it *four years after* the FDA had allegedly reached a decision regarding the inappropriateness of dose adjustment. Without additional evidence of official action, Defendant's later exchanges become largely inconsequential.

Further, Defendant cannot argue that the FDA's inaction regarding the five instances of information exchange constitutes action. Defendant contends that the FDA "ultimately approved the medicine at a fixed dose without any requirement for monitoring" and that "[t]he FDA has repeatedly considered [dose adjustment] since and has never once amended its no-monitoring view." *Id.* at 9. Defendant's evidence, however, does not support that assertion, and the Court will not permit Defendant to advance that argument. As pointed out by Plaintiffs, Defendant has never proposed a label that recommended monitoring or dose adjustment. *Pls.' Reply in Supp. of Omnibus Mot.*, at 10. Short of evidence that both BI officially proposed to the FDA a label

instruction to monitor plasma concentration of Pradaxa and adjust the dose accordingly, and the FDA officially rejected that proposal, Defendant may not argue that the FDA has made a determination regarding monitoring and dose adjustment.

D. Defendant's Motion to Exclude Spoliation and Plaintiffs' Motion for Sanctions

Finally, the Court will address the issues of spoliation and sanctions. Although Defendant's Motion to Exclude Spoliation and Plaintiffs' Motion for Sanctions are distinct motions that make different requests, the Court will analyze them together. The two motions predominately cover the same factual predicates, but request two different actions based upon those facts. Defendant requests that this Court prevent Plaintiffs from presenting evidence about, or discussing, discovery issues in previous cases against BI. Plaintiffs, on the other hand, move this Court to provide an adverse inference charge to the jury due to the same discovery issues that Defendant seeks to exclude from trial.

a. Previous Discovery Issues

The parties premise their respective motions upon two discovery issues. The first involved the loss of Dr. Lehr's files stored on the hard drives of his company devices ("File Loss"). The second involved the loss of emails effectively covering a period of roughly a year for three BI employees ("Email Loss"). With regard to the Email Loss, Plaintiffs' concern focuses primarily on only one of the three doctors, Dr. Martina Brückmann. The Court will address the File Loss and the Email Loss, in turn.

The File Loss occurred within the context of federal multi-district litigation against BI. In that litigation, MDL 2385, plaintiffs had sued BI making similar claims to Plaintiffs' claims in this case: that Pradaxa and its warnings were defective and caused major bleeding events. *See In re: Pradaxa (dabigatran etexilate) Prods. Liab. Litig.*, 883 F.Supp.2d 1355, 1356 (U.S. Jud. Pan.

Mult. Lit. 2012). During the course of that litigation, Chief Judge Herndon of the District Court for the Southern District of Illinois expressed displeasure with BI's apparent failure to comply with discovery obligations. *See In re Pradaxa (dabigatran etexilate) Prods. Liab. Litig.*, No. 3:12-md-2385-DRH-SCW, 2013 WL 6486921, at *2 (S.D. Ill. Dec. 9, 2013). The plaintiffs in that case filed their first motion for sanctions, which Chief Judge Herndon granted in a ruling from the bench, sanctioning BI $20 per case, which totaled $29,540. *Id.* at *3-5. After that ruling, Plaintiffs filed another motion for sanctions, the subject matter of which is relevant here.

In their second motion for sanctions during the course of the MDL, the plaintiffs alleged, among other failures, that BI had failed to maintain the custodial file of Dr. Thorsten Lehr. *Id.* at *9. Dr. Lehr was pharmacometrician who had been employed by BI during the development of Pradaxa. *Id.* In September 2012, Dr. Lehr left BI, taking a job with a university in his native Germany. *Id.* However, Dr. Lehr remained, and apparently is still, contractually involved with BI. *Id.*

As explained by Chief Judge Herndon, despite the fact that Dr. Lehr left his job with BI, BI was under a duty to preserve evidence, but failed to retain Dr. Lehr's custodial file. *Id.* Dr. Lehr had not been subject to the litigation hold because BI had apparently not identified him as a custodian. *Id.* at *9-10. All that remained of Dr. Lehr's custodial file were his emails.[2] *Id.* at *10. Chief Judge Herndon did not find this failure to be innocent. *Id.* at *13. Instead, he found that by "not appl[ying] the hold to Dr. Lehr and now fail[ing] to produce certain of his 'files,' BI had violated "the Court's case management order and [done so] in bad faith." *Id.* at *19. In addition to

[2] A subsequent order identified that Dr. Lehr's "user share" had also been maintained. However, prior to that order, counsel for BI had asserted, in an affidavit, that Dr. Lehr's user share was "not available to be collected." *Ex. D to Def.'s Mot. to Exclude Sanctions*, ECF No. 63-4, at 3. Chief Judge Herndon did confirm that Dr. Lehr's desktop, laptop, and blackberry phone were lost. *Id.* at 4.

sanctioning BI $500 per case—for a grand total of $931,500— and requiring BI to produce its foreign employees to sit for depositions in New York City[3], Chief Judge Herndon also notified the parties that if appropriate, he would issue an order "assessing sanctions pursuant to Rule 37 or the Court's inherent authority." *Id.*

Again, in later order, Chief Judge Herndon issued another shot across BI's bow, advising that "[t]he sanctions specifically being considered by the Court in relation to the Prof. Lehr production are (1) an adverse inference jury instruction . . . and/or (4) deeming certain facts admitted at trial." *Ex. D to Def.'s Mot. to Exclude Sanctions*, at 4. Before actually issuing any of the threatened sanctions, Chief Judge Herndon required that "the plaintiffs [make] a particularized showing of prejudice relating to the Prof. Lehr production." *Id.* at 7. Additionally, the judge wanted "plaintiffs [to] submit briefing to the Court demonstrating the nature and scope of prejudice resulting from [BI's] discovery violations in relation to the Prof. Lehr production." *Id.* at 8. However, before Chief Judge Herndon had an opportunity to decide the ultimate issue of whether or not to issue sanctions, the parties settled.

In their Motion for Sanctions, Plaintiffs request that this Court issue sanctions based upon BI's failure, during the course of the federal MDL, to maintain parts of Dr. Lehr's custodial file

[3] The Seventh Circuit Court of Appeals, upon a writ of mandamus, found that Chief Judge Herndon had "exceeded his authority in ordering the location of the depositions changed to punish Boehringer." *In re Petition of Boehringer Ingelheim Pharms., Inc.*, 745 F.3d 216, 219 (7th Cir. 2014). As a result, the majority of the Seventh Circuit panel ordered that the sanction order be rescinded. *Id.* at 220. However, other than the foreign deposition issue, the Seventh Circuit denied the mandamus petition "in all other respects." *Id.*

Defendant contends that this Court should not consider Chief Judge Herndon's sanctions order because it was rescinded pursuant to the Seventh Circuit's direction, and was never reissued prior to the settlement of the MDL cases in May 2014. *Def.'s Resp. to Pls.' Mot. for Sanctions*, ECF No. 85, at 5, 10. Because this Court does not impose sanctions, which is consistent with its discretion under both its inherent authority and Rule 37(e), the Court will not decide the legal force of Chief Judge Herndon's conclusions in the rescinded order.

when it was under a duty to preserve relevant evidence. *Pls.' Mot. for Sanctions*, ECF No. 71, at 4-7. Supporting this request, Plaintiffs cite to the practical adoption of Chief Judge Herndon's sanction order by two Connecticut Superior Court Judges, in the Connecticut Consolidated Pradaxa Litigation. *Id.* 12-14. The Connecticut judges found Chief Judge Herndon's order binding because orders previously entered in the Connecticut Consolidated Pradaxa Litigation had directed that the parties were to coordinate discovery between the Connecticut litigation and the federal MDL cases. *Def.'s Resp. to Pls.' Mot. for Sanctions*, at 11.

Unlike the scenario with the concurrent proceedings in the federal MDL cases and the Connecticut Consolidated Pradaxa Litigation, discovery in this case did not proceed simultaneously with the federal MDL. Indeed, Plaintiffs filed this action after the federal MDL had been closed. *Pls.' Mot. for Sanctions*, at 2.

Plaintiffs, however, argue that this case has a substantially similar discovery bond as the one that existed between the Connecticut cases and the federal MDL cases. Plaintiffs cite the Report of Parties' Planning Meeting in this case. *Id.* at 2-3, 11-12. In that Report, the parties jointly agreed, and informed the Court, that they would use the discovery exchanged during the course of the federal MDL, and allow for supplementation of that discovery in conjunction with the additional discovery being taken in the resumed Connecticut litigation. *Id.*; *Report of Parties' Planning Meeting*, ECF No. 17, at 2-4. Therefore, Plaintiffs contend that this mutual agreement to be bound by the discovery during the federal MDL, also binds Defendant to again endure any punishment for its discovery-related conduct during the federal MDL. Plaintiffs argue that this Court should not only adopt Chief Judge Herndon's rationale and findings, like the Connecticut state courts, but also that this Court should take the additional step that Chief Judge Herndon did

not have the opportunity to take: issue an adverse jury instruction. The Court, however, declines that invitation.

As an initial matter, given the circumstances, the Court is troubled by the fact that the potentially sanctionable activity did not occur subject to this Court's direction. The objectionable conduct occurred under the watchful-eye of Chief Judge Herndon, in the Southern District of Illinois. The Court has serious reservations about imposing one of the most serious sanctions, an adverse jury instruction, when the actions giving rise to that potential sanction were not within this Court's purview, and those actions did not result in this sanction in the court where the conduct occurred. Although the parties have provided Chief Judge Herndon's order regarding the issue of spoliation and potential sanctions, the Court fears that it cannot fully appreciate aspects of the circumstances giving rise to Chief Judge Herndon's decision. In other words, given the discretionary nature of sanctions imposition, the Court hesitates to impose them when the Court did not observe firsthand the course of conduct that could justify sanctions, and that course of conduct was not subject to this Court's direction.

Plaintiffs' attempt to bind the fate of this Court's actions regarding discovery to these actions taken in the federal MDL fails. Plaintiffs agreed to be bound by the MDL discovery in February 2016. *See generally Report of Parties' Planning Meeting*. However, in December 2013, roughly two years before their agreement, Chief Judge Herndon issued his order finding that BI had avoided discovery obligations in bad faith. Therefore, at the time they agreed that BI's federal MDL discovery (with supplementing) would satisfy discovery obligations, Plaintiffs had been on notice for *two years*, that BI's MDL discovery efforts were deficient. Without caveat and without objection, Plaintiffs made this agreement. In fact, Plaintiffs remained silent regarding this potential

discovery issue until they filed the Motion for Sanctions in April 2018. No motion to compel, nor mention of the MDL discovery dispute or the need for sanctions.

The Court recognizes that in certain instances the effect of discovery improprieties in one case may reverberate throughout subsequent actions that address similar claims against the same group of defendants. However, when that is the case, this Court expects parties to bring that to the attention of the Court earlier in the proceedings. *See Travelers Prop. Cas. Co. v. Mountaineer Gas Co.*, No. 2:15-cv-07959, 2018 WL 1370862, at *5 (S.D.W. Va. Mar. 16, 2018) (Goodwin, J.) ("[A] spoliation motion should be filed . . . as soon as reasonably possible after discovery of the facts that underlie the motion." (quoting *Goodman v. Praxair Servs. Inc.*, 632 F.Supp.2d 494, 508 (D. Md. 2009))). This would allow the Court to potentially take other, less drastic, measures to remedy any prejudice. In this case, however, such forewarning did not occur. By delaying their raising of this issue, Plaintiffs deprived the Court of the opportunity to facilitate the attaining of the information by other means, or to otherwise remedy the loss earlier.

With litigation tactics aside, the Court is not convinced that the loss of part of Dr. Lehr's custodial file has prejudiced Plaintiffs. Indeed, a vast majority of Plaintiffs claims survived summary judgment in this case. *See Knight*, 2018 WL 2470990, at *20. In addition to already possessing evidentiary support for their claims, *see id.* at 13-17, Plaintiffs have failed to clearly elucidate what relevant information is lost due to BI's failure to maintain Dr. Lehr's custodial file. The parties dispute whether Dr. Lehr had a "manuscript" of a research paper that was later published by BI that might have addressed the need to establish a therapeutic range. *Compare Def.'s Resp. to Pls.' Mot. for Sanctions*, at 13-15 *with Pls.' Reply in Supp. of Mot. for Sanctions*, at 3. However, a dispute as to whether or not a potentially relevant document ever existed does not establish prejudice given Plaintiffs' otherwise sufficient evidentiary support for their claims. *See*

Steves & Sons, Inc., 2018 WL 2023128, at *5 (noting that the "burden of proof on a motion for spoliation sanctions is unsettled" but providing that "the general approach of courts in the Fourth Circuit has been to apply the clear and convincing evidence standard, especially where a relatively harsh sanction like an adverse inference is sought").

Likewise, despite Chief Judge Herndon's bad faith findings, the Court cannot make the finding of intentional deprivation of evidence based upon the record. Under the recently amended Rule 37(e), in order to give an adverse instruction, a court must find that a party "acted with the intent to deprive another party of the [lost] information's use in the litigation." Fed. R. Civ. P. 37(e)(2).[4] The Fourth Circuit has yet to provide guidance on the "stringent intent requirement" of Rule 37(e)(2). *Jenkins*, 2017 WL 362475, at *17 (internal quotation marks omitted); *Steves & Sons, Inc.*, 2018 WL 20232128, at *10. However, pre-amendment sanctions case law does instruct that "intent" for the purpose of imposing sanctions is not equivalent to "bad faith." *Buckley v. Mukasey*, 538 F.3d 306, 323 (4th Cir. 2008) ("[T]he district court appears to have committed an error of law by equating the intentional conduct necessary for such an instruction with bad faith . . . ." (citing *Vodusek v. Bayliner Marine Corp.*, 71 F.3d 148, 156 (4th Cir. 1995))). Certainly, a bad faith finding could supply a basis from which to find an intent to deprive. But given the record before this Court, the Court simply cannot conclude that BI's failure to retain information establishes that BI acted with the intent to deprive Plaintiffs of relevant information in this suit. As such, the severe sanction of an adverse inference instruction—the only sanction requested by

[4] The parties, both in their briefing and at the hearing, agreed that Rule 37(e) governed Dr. Lehr's lost information. Although Dr. Lehr may have had some written, non-ESI documents, those non-ESI documents represented a minor and unimportant portion of the information in question. Indeed, in his affidavit, Dr. Lehr confirmed that he rarely had non-electronic notes or documents. *Ex. C to Def.'s Mot. to Exclude Spoliation*, ECF No. 63-3, at 3. Therefore, the Court finds that Rule 37(e) applies to Dr. Lehr's missing information.

Plaintiffs—does not fit the circumstances, and this Court will not impose such a sanction. *See Steves & Sons, Inc.*, 2018 WL 2023128, at *11 (noting that an adverse inference instruction is "a relatively harsh sanction").

The Court also refuses to sanction Defendant for the Email Loss. The Email Loss occurred more recently than the File Loss involving Dr. Lehr. In November 2016, Defendant's counsel notified Plaintiffs' counsel that emails for three BI employees, including Dr. Brückmann, had been inadvertently lost during BI's "transition from one legal hold system to a different legal hold system." *Def.'s Resp. to Pls.' Mot. for Sanctions*, at 5-6. Although this transition resulted in the loss of roughly three years of emails, through remedial efforts, BI reconstituted a vast majority of the emails for a two-year period. *Id.* at 6. This left about one year of lost emails.

As with the situation regarding the loss of Dr. Lehr's information, the Court believes the factual record supports neither a finding of prejudice, nor of an intent to deprive. Although some unknown emails may have been lost, Plaintiffs already possess emails from Dr. Brückmann that appear to support their claims. *See Ex. 35 to Pls.' Resp. to Summ. J.*, ECF No. 51-35, at 1. Plaintiff even used Dr. Brückmann's emails to rebut Defendant's summary judgment motion. *See Pls.' Resp. to Summ. J.*, ECF No. 51, at 19. Additionally, as Defendant has proffered, and as Dr. Brückmann has largely supported, most of Dr. Brückmann's lost emails would have been caught within the litigation hold upon parties who were copied on, or received, the emails, and subsequently produced to Plaintiffs. *Def.'s Resp. to Mot. for Sanctions*, at 17; *Ex. I to Def.'s Mot. to Exclude Spoliation*, ECF No. 63-9, at 6. Therefore, there is no demonstration that Plaintiffs have been deprived of relevant information.

In addition to the lack of prejudice, the nature of the Email Loss fails to support a finding of an intent to deprive. Defendant has represented that the loss of the emails was due to an accident

occurring with the switch of litigation hold software. *Def.'s Resp. to Mot. for Sanctions*, at 16. And Plaintiffs have not submitted any evidence that would substantiate a finding of intent. Simply, with the facts before the Court, and within its discretion, the Court finds neither prejudice, nor intent to deprive, and will not impose Plaintiffs' requested sanctions. Plaintiffs' Motion for Sanction is **DENIED**.

Given that the Court has not made the findings necessary to allow for sanctions, and given the Plaintiffs' otherwise sufficient factual support for their claims, the Court believes that any evidence or argument regarding these previous discovery issues would prejudice Defendant. Additionally, the Court finds that that prejudice substantially outweighs any probative value that the previous discovery issues may have. Therefore, the Court will grant Defendant's Motion to Exclude Spoliation (ECF No. 63), and will prohibit the discussion of previous discovery issues, findings, or sanctions. However, because Plaintiffs have asserted that they do not intent to offer evidence of other litigation, that aspect of Defendant's Motion to Exclude Spoliation will be denied as moot. *See Pls.' Resp. to Def.'s Mot. to Exclude Spoliation*, ECF No. 80, at 1 n.2.

III. CONCLUSION

For the reasons explained above, the Court:

1. **GRANTS** Defendant's Omnibus Motion to Exclude the Opinions of Plaintiff's General Experts (ECF No. 47) only with respect to the exclusion of testimony of Plaintiffs' experts regarding the inference of BI's intent or motive based upon its internal document, and **DENIES** the remainder of the motion;
2. **DENIES** Defendant's Motion *in Limine* No. 2 to Exclude Evidence, Testimony, and Argument on Financial Metrics (ECF No. 64) to the extent that Plaintiffs seek to offer evidence or argument regarding any actual or perceived

economic benefits or disadvantages in Defendant's development and sale of Pradaxa, and **DIRECTS** the parties to obtain leave of the Court before offering evidence of Defendant's profitability or financial condition unrelated to the development and sale of Pradaxa;

3. **GRANTS** Plaintiffs' Omnibus Motion *in Limine* (ECF No. 73) with regard to the exclusion of both (1) Defendant's presenting "good," charitable, or other acts indicative of corporate responsibility, or a general good reputation, that are unrelated to Pradaxa, and (2) Defendant's characterization that the FDA has affirmatively made a decision regarding the appropriateness, need, or lack thereof, for dose adjustment or monitoring, and **DENIES** the remainder of the motion, but will permit Plaintiffs to raise specific objections to the use "FDA label" or similar references during the trial;
4. **GRANTS** Defendant's Motion *in Limine* No. 1 to Exclude Evidence, Testimony, and Argument Regarding Alleged Spoliation Issues, MDL Discovery Sanctions, and Other Litigation (ECF No. 63) with regard to the previous issues, findings, and sanctions related to discovery in previous matters, but **DENIES AS MOOT**, the portion of the motion that seeks to exclude the discussion of other litigation generally; and
5. **DENIES** Plaintiffs' Motion for Spoliation Finding and Adverse Inference Charge (ECF No. 71).

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

ENTER: June 19, 2018

ROBERT C. CHAMBERS
UNITED STATES DISTRICT JUDGE