NO. CPL-HHD CV16-6068484S	:	STATE OF CONNECTICUT
EUGENE ROBERTO	:	SUPERIOR COURT
v.	:	COMPLEX LITIGATION DOCKET
	:	JUDICIAL DISTRICT OF HARTFORD
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., ET AL.	:	SEPTEMBER 11, 2019

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Ruling on Post-Verdict Motions

In May, 2016, the plaintiff, Eugene Roberto, filed this product liability action against the defendants, Boehringer Ingelheim Pharmaceuticals, Inc., and Boehringer Ingelheim International GMBH. The defendants manufacture Pradaxa, an anticoagulant medication designed to prevent strokes in patients with atrial fibrillation, which is an irregular heart rhythm. The gravamen of the complaint is that the label for Pradaxa did not adequately warn about the risk of bleeding. Jury trial commenced on April 30, 2019. On May 17, 2019, a jury returned a verdict in favor of the plaintiff and awarded $42,464.45 in economic damages and $500,000 in noneconomic damages. The jury also found that the plaintiff is entitled to punitive damages.

The plaintiff has filed a postverdict motion for punitive damages, asking the court to determine the amount of the punitive damages award (Docket Entry # 308.00.) The defendants have filed postverdict motions for a collateral source reduction (Entry # 309.00) and for judgment notwithstanding the verdict or to set aside the verdict (Entry # 310.00). The latter motion raises claims that the evidence of various elements of the plaintiff's liability case was insufficient, that the evidence to support the finding for punitive damages was insufficient, that the plaintiff's case is preempted by federal law, and that the court erred in various evidentiary rulings. In this decision, the court rules on these motions and addresses all principal claims raised in order to facilitate any appellate review.

I. SUFFICIENCY OF THE EVIDENCE OF LIABILITY

The defendants' motion for judgment notwithstanding the verdict or to set aside the verdict first challenges the sufficiency of the evidence of various aspects of the liability portion of the plaintiff's case. The undisputed historical evidence is that the federal Food and Drug

Administration (FDA) first approved the Pradaxa label in October, 2010.[1] Pradaxa belongs to a relatively new class of drugs called NOACs, or novel oral anticoagulants, developed to provide an alternative to warfarin (the chemical name for Coumadin) for stroke prevention in patients with atrial fibrillation. See *Knight v. Boehringer Ingelheim Pharmaceuticals, Inc.*, 323 F. Supp. 3d 809, 817 (S.D.W. Va. 2018). "Unlike anticoagulant medications such as warfarin, NOACs ... do not require periodic blood testing or impose dietary restrictions on users." *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 652 (S.D.N.Y. 2017). The other FDA-approved NOACs are Eliquis, Xarelto, and Savaysa. Id., 652 n.5.

On or about August 3, 2011, the plaintiff, after conferring with his cardiologist, Michael D'Angelo, switched from warfarin to Pradaxa 150 milligrams (mg) twice a day. On or about January 29, 2014, the plaintiff experienced a life-threatening gastrointestinal bleed from a stomach ulcer, resulting in his hospitalization for nine days. The plaintiff fully recovered physically but switched his medication to Eliquis.

The same standards govern motions for judgment notwithstanding the verdict as motions for a directed verdict because the former motion is "not a new motion, but [is] the renewal of [the previous] motion for a directed verdict." (Citation omitted; internal quotation marks omitted.) *Demond v. Project Service, LLC*, 331 Conn. 816, 834, 208 A.3 d 326 (2019). "A trial court may set aside a verdict on a finding that the verdict is manifestly unjust because, given the evidence

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[1]The United States Supreme Court has stated: "Although we commonly understand a drug's 'label' to refer to the sticker affixed to a prescription bottle, in this context the term refers more broadly to the written material that is sent to the physician who prescribes the drug and the written material that comes with the prescription bottle when the drug is handed to the patient at the pharmacy.... These (often lengthy) package inserts contain detailed information about the drug's medical uses and health risks." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672-73 (2019).

presented, the jury mistakenly applied a legal principle or because there is no evidence to which the legal principles of the case could be applied. ... A verdict should not be set aside, however, where it is apparent that there was some evidence on which the jury might reasonably have reached its conclusion.... This limitation on a trial court's discretion results from the constitutional right of litigants to have issues of fact determined by a jury.... Upon issues regarding which, on the evidence, there is room for reasonable difference of opinion among fair-minded [people], the conclusion of a jury, if one at which honest [people] acting fairly and intelligently might arrive reasonably, must stand, even though the opinion of the trial court ... be that a different result should have been reached.... [I]f there is a reasonable basis in the evidence for the jury's verdict, unless there is a mistake in law or some other valid basis for upsetting the result other than a difference of opinion regarding the conclusions to be drawn from the evidence, the trial court should let the jury work [its] will." (Citations omitted; internal quotation marks omitted.) *Deas v. Diaz,* 121 Conn. App. 826, 841, 998 A.2d 200, cert. denied, 298 Conn. 905, 3 A.3d 69 (2010). "[T]he role of the trial court on a motion to set aside the jury's verdict is not to sit as a seventh juror, but, rather, to decide whether, viewing the evidence in the light most favorable to the prevailing party, the jury could reasonably have reached the verdict that it did...." (Internal quotation marks omitted.) *Weihing v. Preto-Rodas,* 170 Conn. App. 880, 884, 155 A.3d 1278 (2017). "In assessing the evidence, the court should weigh both direct and circumstantial evidence, including all reasonable inferences to be drawn therefrom." (Internal quotation marks omitted.) *Kriz v. Coldwell Banker Real Estate*, 67 Conn. App. 688, 692, 789 A.2d 1091 (2002).

A. CAUSATION

1. Cause in Fact

The defendants first challenge the sufficiency of the evidence on cause in fact. The court charged as follows on this issue: "The plaintiff has the burden of proving that BI's conduct was the legal cause of plaintiff's injuries. Legal cause has two parts. You will find that your verdict form tracks my discussion of these issues. The first part is cause in fact. The test for cause in fact in this case is, simply, would the injury have occurred were it not for the allegedly inadequate warnings and instructions. To prove cause in fact, the plaintiff must prove that, with additional warnings or instructions, Dr. D'Angelo would have decided either not to prescribe Pradaxa or would have altered his discussion of the medication with Mr. Roberto in a way that would have led Mr. Roberto to decide not to take Pradaxa and not experience a bleed of similar severity. Thus, cause in fact actually breaks down into two subparts. The first subpart, which you will see as question number two on your verdict form, asks whether the plaintiff has proven that, with the additional warnings or instructions, Dr. D'Angelo would have decided either not to prescribe Pradaxa or would have altered his discussion of the medication with the plaintiff in a way that would have led Mr. Roberto to decide not to take Pradaxa. The second subpart, which you will see as question number three on your verdict form, asks whether the plaintiff has proven that he would not have experienced a bleed of similar severity on a different anticoagulant. Stated differently, in order to show cause in fact, the Plaintiff — given that his atrial fibrillation diagnosis required him to take some sort of anticoagulant — must also prove at trial that he would not have experienced a bleed of similar severity if his prescribing doctor had changed his prescription to a different anticoagulant. The fact that Mr. Roberto was injured, standing alone, is

insufficient to prove that BI's conduct was a cause in fact of his injury."

a. *Whether Inadequate Labeling Caused the Injury*

The defendants challenge the sufficiency of the evidence on both subparts of cause in fact. The first subpart addresses whether a labeling change would have affected the decision to prescribe Pradaxa. According to the charge, there were, in turn, two ways that the plaintiff could prove the first subpart. The first way was to show that, with a label change, "Dr. D'Angelo would have decided ... not to prescribe Pradaxa." The second way is if D'Angelo "would have altered his discussion of the medication with Mr. Roberto in a way that would have led Mr. Roberto to decide not to take Pradaxa." The court holds that, while there was insufficient evidence on the first part, there was minimally sufficient evidence on the second part.

With regard to the first part of the cause in fact inquiry, there is no testimony that, with a label change, D'Angelo would have decided not to recommend or prescribe Pradaxa. Indeed, D'Angelo testified clearly that he "[stands] behind" his decision to prescribe Pradaxa and that, in prescribing Pradaxa, he made "the right decision." (Ct. Ex. 11, p. 45; Ct. Ex. 13, p. 52.) Even when presented with a list of the plaintiff's proposed warnings, D'Angelo agreed that he could not "say that they would have changed Mr. Roberto's use of Pradaxa ...." (Ct. Ex. 11, pp. 2, 39-40.)

The plaintiff relies on testimony that D'Angelo would follow guidelines, recommendations, and the package insert. (Pl. Br., pp. 8-9.) Even that testimony, as applied to the proposal to test or monitor the patient's blood periodically to determine Pradaxa levels (blood monitoring), was equivocal.[2] Further, the plaintiff's selections from the testimony do little more

[2]On the subject of blood monitoring, which formed paragraphs d and e of the plaintiff's proposed labeling change, D'Angelo testified as follows:
Q "Okay. So based on an amended label that's instructing you to assess your patient's Pradaxa

than establish that D'Angelo would do what any responsible doctor would do. The testimony tells us nothing about how the doctor would apply the specific guidelines and standards in this particular case. There is no testimony that, as a result of the changes in the label that the plaintiff proposed, D'Angelo would have changed his recommendation or prescription of Pradaxa. On the contrary, as mentioned, D'Angelo provided the opposite testimony that, even given the plaintiff's proposal, he would not have done so. The jury could not reasonably make the leap from testimony that D'Angelo would not have changed his prescription to a conclusion that he would have changed his prescription. Thus, there was insufficient evidence to prove that, with a label change, D'Angelo would not have prescribed Pradaxa.

The closer question concerns the second way of proving the first subpart, which raises the issue of whether a labeling change would alter the doctor's advice in a way that would have led the plaintiff to change his decision to take Pradaxa. The background facts are essentially undisputed. The plaintiff had a history of atrial fibrillation and GERD, or gastroesophageal reflux disease. Because atrial fibrillation creates a risk that blood clots will form in the heart, travel to the brain, and cause a stroke, the plaintiff had been taking the anticoagulant warfarin since approximately 2005. (Ex. 2000, pp. 116-17.) The plaintiff testified that, while waiting at the doctor's office, presumably sometime in 2011, he saw a pamphlet on Pradaxa and asked a nurse about it. Ultimately, the plaintiff had a discussion with D'Angelo and decided to change to Pradaxa. (5/7/19 p.m. Tr., pp. 40-41, 62.) D'Angelo's August, 2011 medical note similarly

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level, and given your practice as you've previously described, that you typically follow the labeled instruction, would you follow an instruction or not follow an instruction?
A "I follow labels and instructions. I am confused as to section D and E, specifically what levels you're referring to, because there's certain assays that are recommended currently to follow." (Ct. Ex. 13, p. 30.)

indicates that the plaintiff requested the change from warfarin to Pradaxa. "We discussed the risk/benefits of this medication and he would prefer to change to Pradaxa for ease of use with consideration for his extended periods of time in New Mexico." (Ex. 2000, p. 105.)[3]

The plaintiff then provided the following testimony on direct examination:

Q "Now, Gino, if you had known in August of 2011 that there was an increased risk of bleeding for someone with GERD on Pradaxa, would you have asked to switch?

...

A "No way.

...

Q "Do you remember the question or do I have to try to remember it?

A "The answer is still, No way."

(5/7/19 p.m. transcript, p. 43.).

Thus, according to the evidence, if the plaintiff had known that there was an increased risk of bleeding for a patient with a history of GERD, he would not have asked to switch to Pradaxa. Although this testimony relied on the benefit of hindsight, the testimony was admissible and the jury was entitled to credit it.

Logically, the question becomes whether the plaintiff would have learned about an increased bleed risk for Pradaxa patients with a history of GERD if this information were in the Pradaxa label. The plaintiff in fact proposed that the Pradaxa label contain warnings that "GERD increases a patient's bleed risk" and that "GERD and age over 75 put your patient at risk of

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[3]The plaintiff and his wife lived in the Buffalo area and preferred to travel to warmer areas in the winter.

excessive exposure to Pradaxa." (Ct. Ex. 12.) On this point, the plaintiff offers the following testimony from D'Angelo:

Q "And is that standard for you, that you would discuss the benefit/risks of the medicine with the patient?

A "It is my practice.

Q "Does that include risks in the label?

A "Yes.

Q "And would you have weighed those risks and benefits yourself before making a recommendation?

A "Typically, yes.

Q "And your best understanding is you did so here?

A "That is my practice."

(Ct. Ex. 11, p. 8.)

Although this testimony is general in nature, the jury could have reasonably inferred from it that D'Angelo would have mentioned the increased bleed risks for patients with a history of GERD if the label had disclosed that risk. The likelihood that D'Angelo would have at least mentioned this issue (even if not providing a formal warning) when discussing the matter with the plaintiff is enhanced by the fact that D'Angelo was well aware of the plaintiff's history of GERD. (Ct. Ex. 13, pp. 19-20.) There is no specific contrary testimony that D'Angelo would not have informed the plaintiff of information in the label that a history of GERD may increase bleeding risk.

As mentioned above, the defendants rely on testimony that, when presented with the list of

the plaintiff's proposed warnings, D'Angelo agreed that he could not "say that they would have changed Mr. Roberto's use of Pradaxa ...." In addition, D'Angelo testified as follows:

Q "Is there any change you've made to how you warn patients as a result of what Mr. Moskow showed you when he had the chance to have his case in front of you in his deposition in 2017?

A "No."

(Ct. Ex. 11, p 40.)

This testimony, like that relied upon by the plaintiff, is also general and does not specifically mention GERD. Further, the colloquy does not foreclose the possibility that D'Angelo would have at least passed on the new information about GERD or that it may have changed the discussion without changing "how [he warns] patients."

The matter is a close call but, because the court must construe the evidence in a light most favorable to the plaintiff, the court concludes that there was sufficient evidence of causation on this theory. Given the reasonable inference that D'Angelo would have mentioned the increased bleed risk for patients with a history of GERD, and the plaintiff's clear testimony that he would not have asked to change to Pradaxa if his doctor had mentioned this increased risk of bleeding, the jury could reasonably have concluded that the plaintiff, under these circumstances, would have elected not to take Pradaxa. Thus, there was at least minimally sufficient evidence that the plaintiff met his burden, under the court's instructions, of proving causation by showing that, with a label change, he would have "[decided] not to take Pradaxa."[4]

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[4]The plaintiff also testified that D'Angelo originally showed him a "medication guide" for Pradaxa and that the plaintiff read the medication guide the first few times that he picked up a Pradaxa prescription. (5/7/19 p.m. Tr., pp. 64-66.) The medication guide is a part of the label written for patients. (Ex. 5881, pp. 10-13.) The Pradaxa medication guide contains a warning that the plaintiff "may have a higher risk of bleeding if you take PRADAXA" and the patient has

The defendants additionally argue that the absence of warnings about GERD cannot constitute a cause in fact of the plaintiff's bleed unless GERD caused the bleed, which it purportedly did not do. However, the defendants' argument focuses on the adequacy of the warning, not the separate element of causation. With regard to adequacy, it is true that the court charged in a section entitled "Breach of Duty to Provide Adequate Warnings" that "the alleged warning deficiencies must be related to the type of injury suffered by the Plaintiff. If Mr. Roberto did not experience the type of harm that an adequate warning would have addressed, then BI is not liable for failure to warn." But this requirement was satisfied in this case by the fact that the plaintiff suffered a bleed, which is exactly the type of harm that the plaintiff proposed to warn about for patients with a history of GERD. In any event, this requirement is separate from the element of causation. For that element, the court charged, as discussed, that the plaintiff must prove at least that additional warnings would have altered the doctor's discussion in a way that would have led the plaintiff to decide against taking Pradaxa. Here, according to the evidence, any reference by D'Angelo to an increased bleed risk for patients with a history of GERD would have persuaded the plaintiff not to change from warfarin to Pradaxa. Thus, there is sufficient evidence on the element of cause in fact.[5]

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various characteristics such as "over 75 years old" or "kidney problems." (Ex. 5881, p. 10.) If the medication guide, being part of the label, had also noted a history of GERD as a risk factor, as the plaintiff proposes, the plaintiff, according to his own testimony – which the court must accept – would have then read about this additional risk and decided not to take Pradaxa. Again, although no witness expressly states this theory of causation, the court can support this theory by construing the evidence in the plaintiff's light and drawing all reasonable supporting inferences.

[5]In contrast, there is no similar testimony from the plaintiff that he would have rejected Pradaxa if he learned that its label required blood monitoring. Thus, there is insufficient evidence to sustain the verdict on the theory that the absence of warnings about blood concentration and monitoring was a cause in fact of the plaintiff's injury.

b. *Whether Pradaxa Caused a More Severe Bleed*

According to the court's instructions, the second subpart of cause in fact required the plaintiff to prove that "he would not have experienced a bleed of similar severity on a different anticoagulant ...." Plaintiff's expert gastroenterologist, Stuart Finkle, testified on direct examination that the plaintiff would not have developed, or at least was less likely to develop, a similar life-threatening bleed on a different anticoagulant, in part because the plaintiff in fact did not have a similar bleed while on either warfarin or Eliquis. (5/6/19 a.m. Tr., pp. 23, 97-98.) Although the defendants challenge Finkle's methodology and reasoning, Finkle's credibility, like that of any expert, was ultimately for the jury to consider. There was sufficient evidence on the second subpart of the cause in fact inquiry to support the jury's verdict.

2. Proximate Cause

The defendants also attack the sufficiency of evidence of proximate cause. The court charged as follows on this issue: "The second part of legal cause is called proximate cause, which is the basis of question four on your verdict form. The plaintiff must prove that the Pradaxa was a proximate cause of plaintiff's injuries. Pradaxa was a proximate cause of an injury if it was a substantial factor in bringing the injury about. In other words, if Pradaxa contributed materially and not just in a trivial or inconsequential manner to the production of the injury, then Pradaxa was a substantial factor. Proximate cause does not require the plaintiff to remove from the realm of possibility all other potential causes of the injury. The plaintiff does not have to prove that Pradaxa was the only factor that led to the injuries claimed – or even the most significant factor – in order to prevail. Rather, the plaintiff need only establish that Pradaxa contributed substantially to his bleed."

The defendants argue that a gastric ulcer caused the plaintiff's bleed and that there was no evidence that Pradaxa caused the gastric ulcer. Even if the court accepted this point, it would not negate all evidence of proximate cause. The evidence established that the plaintiff experienced a life-threatening bleed for which he was hospitalized for at least nine days. As suggested by the charge, the issue is not necessarily whether Pradaxa caused the bleed but whether Pradaxa "contributed substantially to his bleed." This standard fully allows the plaintiff to prove proximate cause by showing that Pradaxa, even if not the original cause of the bleed, made it more severe. As stated in the cause in fact section of the charge, the question is whether, without Pradaxa, the plaintiff would have "[experienced] a bleed of similar severity."

The plaintiff supplied such proof. Stuart Finkle, the plaintiff's gastroenterology expert, testified that the plaintiff would not have developed, or at least was less likely to develop, a similar life-threatening bleed on a different anticoagulant. He added with reference to the bleed that Pradaxa "[m]ade it worse, exacerbated it." (5/6/19 a.m. Tr., p. 92.) Even Laurel Fisher, the defendant's gastroenterology expert, admitted that, no matter what the cause of the ulcer, Pradaxa could make the injury bleed more extensively. (5/13/19 p.m. Tr., p. 48.) Thus, the plaintiff supplied ample proof of proximate cause.

B. ADEQUACY OF THE WARNINGS

At trial, the plaintiff's sole claim on the merits was that the warnings on the Pradaxa label were not adequate. The defendants contend that the warnings on the Pradaxa label were adequate as a matter of law and that, therefore, the court should enter judgment for the defendants. The court rejects this contention. The adequacy of the warnings is ordinarily an issue of fact. See *Erony v. Alza Corp.*, 913 F. Supp. 195, 199 (S.D.N.Y. 1995) (under New York law); *Knight v.*

Boehringer Ingelheim Pharmaceuticals, Inc., 323 F. Supp. 3d 809, 830–31 (S.D.W. Va. 2018) (under West Virginia law in a Pradaxa case). See also *Sharp v. Wyatt, Inc.*, 31 Conn. App. 824, 834, 627 A.2d 1347 (1993), aff'd, 230 Conn. 12, 644 A.2d 871 (1994) ("Whether a product is defective under § 52–572q is a question of fact.") In this case, both of plaintiff's experts, Laura Plunkett, a pharmacologist and toxicologist, and Stuart Finkle, a gastroenterologist, testified that the warnings were not adequate in various ways. The jury could have credited this testimony. Accordingly, as a general matter, there was sufficient evidence that the warnings were not adequate to support the verdict.

The defendants point specifically to the fact that the Pradaxa label does refer to GERD. The label states that "Patients on PRADAXA 150 mg had an increased incidence of gastrointestinal adverse reactions (35% vs. 24% on warfarin). These were commonly ... gastritis-like symptoms (including GERD ....)" (Ex. 94, § 6.1.) The label also directs physicians to "[i]nstruct patients to call their health-care provider if they experience any signs or symptoms of dyspepsia or gastritis [such as] ... GERD (gastric indigestion.)" (Ex. 94, § 17.3.) This language may adequately warn doctors that GERD can constitute an adverse reaction to Pradaxa. However, the language does not achieve the separate purpose of advising doctors that a history of GERD is a risk factor for a different adverse reaction – bleeding. Thus, the jury could reasonably have found that the GERD warnings were not adequate.[6]

[6]The defendants also argue that any deficiency in the warnings on GERD was irrelevant because GERD had no relation to the plaintiff's injury. As the court has previously stated, however, if plaintiff's history of GERD made a bleed more likely, then warnings concerning GERD were relevant.

II. PUNITIVE DAMAGES

A. SUFFICIENCY OF THE EVIDENCE

General Statutes §52-240b provides in product liability actions that "[i]f the trier of fact determines that punitive damages should be awarded, the court shall determine the amount of such damages not to exceed an amount equal to twice the damages awarded to the plaintiff." The jury determined that punitive damages should be awarded. The defendant's motion for judgment and to set aside the verdict challenges the sufficiency of the evidence to support the jury's decision to have the court determine the amount of punitives.

The court charged the jury that it could find punitive damages if it found that the defendants acted with a "reckless disregard for the safety of Pradaxa users and that the harm suffered by the plaintiff resulted therefrom." The basis of the charge was § 52-240b, which also states: "[p]unitive damages may be awarded if the claimant proves that the harm suffered was the result of the product seller's reckless disregard for the safety of product users, consumers or others who were injured by the product."[7]

The court finds that there was sufficient evidence of punitive damages based primarily on the testimony of Laura Plunkett, the pharmacologist and toxicologist who testified for the plaintiff. Plunkett had reviewed a variety of emails and statements by scientists working for the defendants that, in addressing and rejecting the need for blood monitoring, refer to matters such as "competitive disadvantage" or "marketing." What follows are three excerpts from Plunkett's

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[7]Section 52-240b states in full: "Punitive damages may be awarded if the claimant proves that the harm suffered was the result of the product seller's reckless disregard for the safety of product users, consumers or others who were injured by the product. If the trier of fact determines that punitive damages should be awarded, the court shall determine the amount of such damages not to exceed an amount equal to twice the damages awarded to the plaintiff."

direct examination.

Q "And specifically with regard to the decision not to share information with U.S. doctors regarding the importance of blood levels, what documents -- documentary statements have you seen that say the reason why?

A "I've seen statements that the reasons deal with a competitive disadvantage and that it may hurt sales."

(5/1/19 p.m., p. 28.)

Q "How, if at all, is that statement consistent or inconsistent with what you've previously told the jury that you've seen documents that show that the company was making decisions based on sales instead of patient safety?

A "I think this is directly supportive of that. Absolutely right."

(5/2/19, p. 11.)

Q "You made that statement that you had seen evidence that decisions were, I have, Based on patient safety. Is that what you meant?

A "I'm saying that patients should be based on safety – patient safety, not on commercial concerns or not on sales.

Q "And did you have an opportunity to show the jury evidence of what you believe relates to that?

A "Yes. And so that might be a separate opinion. Because I'm saying you should do it based on safety. But there's some evidence to show that it's my opinion that the evidence shows that commercial concerns or sales were driving decisions about the -- about failure to provide physicians with that information on safe levels of Pradaxa in blood.

...

Q "Sales over safety?

A "The sales -- no. They -- they were putting the sales over safety. You should be putting safety over sales. So either way you want to look at it."

(5/2/19 p.m. Tr., pp. 26-27.)

If the jury credited this testimony, they could reasonably have concluded that the defendants put safety over sales and acted in "reckless disregard for the safety of product users ...." Therefore, there was sufficient evidence to support the award of punitive damages.

B. AMOUNT OF PUNITIVES

The next issue, as raised in plaintiff's motion for punitive damages, is the amount of punitives. Section 52-240b creates a two-step process for awarding punitives. In the first step, the trier of fact – here the jury – decides whether "punitive damages should be awarded ...." In the second step, the court decides "the amount of such damages ...." General Statutes § 52-240b. There is little dispute, based on the language of the statute, that the court has discretion in setting that amount. The plaintiff's brief in fact acknowledges that "the amount of punitive damages is within the discretion of the trial court ...." (Pl. Motion for Punitive Damages, Entry # 308.00, pp. 1-2.) See also *Arnone v. Enfield*, 79 Conn. App. 501, 522, 831 A.2d 260, cert. denied, 266 Conn. 932, 837 A.2d 804 (2003) ("An award of punitive damages is discretionary....") Presumably, on the second step, the court must act independently and in good conscience, guided by its own evaluation of the evidence.

At the outset, the court must state that it simply does not credit the testimony of Dr. Plunkett on this issue. Although Plunkett was entitled to review company documents and explain the process for developing Pradaxa, the court believes that Plunkett engaged in unreliable mind-

reading in concluding that the company put sales over safety. The court views the company's documents and emails very differently. To begin with, it is entirely appropriate for employees of a for-profit company such as Boehringer Ingelheim (BI) to consider topics such as cost and sales. If a pharmaceutical company cannot make a profit selling a drug, the company would likely withdraw the drug, with all its attendant benefits, from the market.[8] Further, as best as the court can recall, all of the expert witnesses who addressed the matter agreed that internal debate within a company is a positive activity that improves decision-making. Singling out comments made during these internal debates is not necessarily an accurate way of determining the company's position. [9] On the other hand, when one focuses on the ultimate decision-makers within the company, such as Drs. Jeffrey Friedman, therapeutic area head, cardiovascular (Ex. 27),[10] Dr. Siegfried Eberle, chief safety officer for Pradaxa (5/1/19 a.m. Tr., p. 5),[11] and Dr. Klaus Dugi,

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[8]Although in its summary judgment ruling the court stated that the company emails created a fact issue for the jury on punitives, the court made no credibility determinations and did not have the benefit of seeing and reading the entire testimony.

[9]Paul Zei, the defendant's expert cardiologist and physiologist, testified sensibly as follows: "And so for me, you know, what happens sort of behind the scenes of a company is less relevant than what they come up with after their own internal discussions and face front with us as physicians and researchers." (5/14/19 a.m. Tr., p. 36.)

[10]In rejecting a proposed manuscript that discussed a therapeutic range for Pradaxa blood concentrations, Dr. Friedman stated that the publication was "not representative of the appropriate medical and scientific interpretation of these data." (Ex. 27, p. 1.)

[11]Dr. Eberle testified as follows:
Q "When you warn about those factors that increase the risk of bleeding, including age, including renal function, including other medicines they may be taking at the same time, confounders, is there something extra you get by warning about blood concentration levels in your view?
A "I think there would be no extra to it.
Q "You've given the important information?
A "We provide all the information for the safe use, as I see it."
(Ct. Ex. 8, p. 7.)

corporate head of medicine (5/9/19 a.m. Tr., p. 46),[12] there is no evidence that profits or greed was the driving force in rejecting blood monitoring. Based on the statements of these corporate leaders, it was the lack of a scientific or practical basis for monitoring, rather any economic factors, that drove the decision.

This case is not one in which a company, motivated by greed, proceeded to ignore safety standards, defy government regulations, or disregard scientific literature in order to put an unreasonably dangerous or socially worthless product on the market. On the contrary, all experts agreed that Pradaxa provides significant benefits in reducing the risk of a stroke, with all its devastating consequences. Fortunately, the plaintiff himself achieved this benefit and did not suffer a stroke.[13]

Since the discovery of the dabigatran molecule in the 1990s, the defendants went to elaborate lengths and expense to develop and test the product, culminating in a clinical trial (known as the RE-LY trial), involving some 18,000 people, extensive debate at the Food and Drug Administration (FDA), and finally approval in 2010 (Ex. 94, § 14; Ex. 3247, p. 2; Ex. 5827, p. 3; Ct. Ex. 10, p. 3.) The FDA has never recalled the product and instead has approved the label some eighteen times subsequently (Ex. 6327.) The sixteen page label itself explicitly and

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[12]Dr. Dugi testified as follows:
Q "And in your view, is it possible to describe an optimal therapeutic range that would apply to all patients?
A "No. I think it's fair to say that we and others, so experts within Boehringer and also external experts, have, yeah, spent considerable time and effort to define such a, as you say, sweet spot, but we have been unable and they have been unable to do that."
(Ct. Ex. 26, p. 21.)

[13]Dr. Zei testified that stroke is the fifth leading cause of death in the United States, that, if not fatal, a stroke can cause serious long-run disability, and that patients with atrial fibrillation, such as the plaintiff, tend to have particularly severe strokes. (5/14/19 a.m. Tr., pp. 47-55.)

repeatedly warns of the very consequences that the plaintiff suffered: "Pradaxa can cause serious and, sometimes, fatal bleeding" and that there was a greater rate of gastrointestinal bleeding than in patients receiving warfarin. (Ex. 94, p. 1, § 5.2, p. 12.) The company has shared its research and sponsored more. Even without more, these facts should preclude an award of any significant punitive damages. See *Johannsen v. Zimmer, Inc.*, No. 3:00CV2270 (DJS), 2005 WL 756509, at *11 (D. Conn. Mar. 31, 2005)(in product liability action, no basis for punitive damages where, among other things, no evidence that the defendant "failed to properly comply with federal Food and Drug Administration regulations.")

There are, however, additional considerations that weigh against an award of significant punitive damages. As discussed, the plaintiff focused on two general labeling deficiencies: the absence of a warning that a history of GERD increases the risk of bleeding, and the absence of warnings and information about testing for excessive Pradaxa concentration in the blood. While there was a battle of the experts on the GERD issue, the fact that the defendants presented at least one medical expert – Paul Zei, a highly-credentialed cardiologist and physiologist – who testified that additional warnings were not necessary renders it simply illogical to conclude that the defendants acted with reckless disregard of patient safety.[14] On the blood testing issue, the plaintiff presented Dr. Plunkett, who is a pharmacologist and toxicologist but not a medical doctor. They did not offer any medical doctor who supported their position. Of the many medical articles introduced at trial, not one of them supported the notion of periodic blood testing,

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[14]After discussing GERD and other aspects of the plaintiff's history, Zei testified as follows:
Q "Based on what you know about Pradaxa today, do you believe that the Pradaxa label appropriately advised Dr. D'Angelo of the relevant risks of the medicine?
A "Yes, I do." (5/14/19 a.m. Tr., pp. 105-08, 147.)

assessment, or monitoring in Pradaxa patients. On the contrary, there was medical literature offered by the defendants that explicitly counseled against blood monitoring. (Ex. 3247, Journal of American Cardiology, p. 8: "There is no single plasma concentration range that provides optimal benefit risk for all patients."); (Ex. 6085, American Heart Journal, p. 8: "Routine PK-PD measurements ... cannot currently be recommended because of lack of reliable tests, lack of clinical evidence of benefit, and lack of data to guide appropriate dosing.") Further, the defendants submitted all of its RE-LY trial data concerning blood level assessment to the FDA; (5/3/19 a.m. Tr., p. 104); and, as a result, the FDA approved language in the label that states: "Generally, the extent of anticoagulation does not need to be assessed." (Ex. 94, § 2.2.) As mentioned, none of the other NOACs requires blood monitoring.[15]

Unless the defendants are required to ignore all of these experts, articles, authorities, and examples, there is no basis for any significant punitive damages. Accordingly, the court awards attorney's fees in the amount of $1. Cf. *Wagner v. Clark Equipment Co.*, 243 Conn. 168, 200, 700 A.2d 38 (1997) ("[a] trial court can certainly, and should not hesitate to, decide in a given case that the evidence proffered on the issue [of punitive damages] is insufficient to be submitted to a jury for its determination.") (Internal quotation marks omitted.) See also *L & L Services, Inc. v. Com-Pak Food Marts of Florence, Inc.*, 575 So. 2d 1094, 1095 (Ala. 1991) (affirming jury's award of $1 in punitive damages); *Stern Enterprises v. Plaza Theaters I & II, Inc.*, 105 Ohio App. 3d 601, 605, 610, 664 N.E.2d 981(1995) (affirming court's award of $1 in punitive damages).

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[15]Ironically, in litigation claiming that the warnings for Eliquis were inadequate, the plaintiffs in that case referred to Pradaxa as "this safer alternative NOAC." *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 668–69 (S.D.NY. 2017).

III. PREEMPTION

The defendants' principal argument for setting aside the verdict is that federal law – here the federal Food, Drug and Cosmetic Act (FDCA); 21 U.S.C. §301 et seq. – preempts the plaintiff's state law product liability and failure to warn claims. This issue originally arose on the defendant's motion for summary judgment. (Entry # 128.00.) The court denied the motion on the ground that there were genuine issues of material fact. (Entry # 128.86). The defendants renewed their preemption arguments at the close of the plaintiff's case in a motion for a directed verdict. (Entry # 298.00.) The court reserved decision. See Practice Book § 16-37. The defendants have again raised the preemption issue in their motion for judgment notwithstanding the verdict and to set aside the verdict. On July 17, 2019, the court heard approximately two and one-half hours of argument on preemption. The court will now decide this issue based on the briefs submitted for all three motions, which are extensive, as well as all of the exhibits cited in these briefs. (Entry # 327.00.)[16]

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[16]The plaintiff objected to reconsideration of the preemption issue at the postverdict motion stage on the ground that "the Defendants withdrew the matter from the jury's consideration and reserved the issue for appeal ...." (Entry #328.00; see also 7/17/19 Tr., pp. 47-48.) However, three days after the verdict in this case, the United States Supreme Court, as will be discussed, decided that preemption in this context is a question of law for the court to decide. *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672, 1679 (2019). That being the case, the court views it as its obligation to decide the preemption issue in the first instance rather than merely pass it on to the appellate courts or have the parties waste resources taking an appeal that would result in a remand to this court to decide the very matter that the court can decide today.

In a written pleading, the plaintiff added the following comment: "once the Court advised that, notwithstanding Plaintiff's Objection, the Court would reconsider its ... ruling regarding preemption, the Plaintiff preserved his objection but agreed that the Court should consider the entirety of the briefing and exhibits on the preemption issue as is reflected in ... Order [# 327.00.] (Entry # 328.00.) Although the defendants agreed generally with this procedure, the defendants have voiced and briefed an objection to the court's consideration of the declaration of Dr. Plunkett, which the plaintiff initially attached to an April 11, 2019 supplemental brief on

At the outset, the court must set forth the general doctrine of preemption and the particular type of preemption raised here, which is called conflict or impossibility preemption. "Preemption comes in three forms.... First is express preemption, which occurs when Congress clearly declares its intention to preempt state law.... Second is implied preemption, which occurs when the structure and purpose of federal law shows Congress's intent to preempt state law.... [T]he third form [is] called conflict or impossibility preemption. Conflict preemption occurs when there is an actual conflict between state and federal law such that it is impossible for a person to obey both.... When that is true, federal law controls and the state-law tort claims must be dismissed." (Citations omitted; internal quotation marks omitted.) *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 811 (7th Cir. 2018), cert. denied, 139 S. Ct. 2636 (2019). Accord *Metcalf v. Fitzgerald,* 333 Conn. 1, 9, ___ A.3d ___ (2019). Alternatively stated, "[t]he Supremacy Clause establishes that federal law 'shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding' .... Where federal and state law conflict – that is, where it is impossible for a party to follow both federal and state law – state law must give way." (Internal quotation marks and citations omitted.) *Gibbons v. Bristol-Myers Squibb Co.,* 919 F.3d 699, 707-08 (2d Cir. 2019).

The defendants' principal preemption argument is that, between the October, 2010 launch date for Pradaxa and the January, 2014 date of the plaintiff's bleed, there was no relevant "newly

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preemption. (Entry # 278, Ex. R; Entry # 282, p. 8 n.17.) The court will adhere to its decision that it will consider all exhibits cited in the papers but, as stated in its order, the court will give any exhibit the weight it is due based on its relevance, specificity, apparent reliability, and any other pertinent consideration, including those outlined in the defendants' objection. (Entry # 327.00.)

acquired information" about Pradaxa that, under federal law, would allow them to change the Pradaxa label. The defendants, in some instances, make an alternative argument that there was "clear evidence" that the Food and Drug Administration (FDA) would have rejected a proposed labeling change. Therefore, according to the defendants, it was impossible to comply with the plaintiff's state law claim that the warnings in the label were inadequate and that the defendants should have revised their label to include the plaintiff's proposals for additional warnings. The court now examines these issues in detail.

A. BACKGROUND

1. The Changes Being Effected (CBE) Regulation

The Second Circuit has provided the following introduction to the preemption issues in this area:[17] "The federal government regulates the manufacture, labeling, and sale of pharmaceuticals pursuant to the FDCA. 21 U.S.C. § 301 et seq.... To bring a drug to market, a manufacturer must file a new drug application, which must explain the drugmaker's tests and studies, demonstrate that the drug is 'safe for use under the conditions prescribed,' and include proposed labeling language. 21 U.S.C. § 355(b)(1)(A), (b)(1)(F), (d). The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label.

"The FDA can direct a pharmaceutical manufacturer to change a drug's label after it has entered the market, see 21 U.S.C. § 355(o)(4), but manufacturers, not the FDA, bear primary responsibility for their drug labeling at all time .... Nevertheless, drug manufacturers are limited in their ability to unilaterally change the labels on their products. Specifically, to make a change

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[17]Connecticut state courts afford "particularly persuasive weight" to decisions from the Second Circuit in the interpretation of federal statutes. See *Webster Bank v. Oakley*, 265 Conn. 539, 555 n.16, 830 A.2d 139 (2003), cert. denied, 541 U.S. 903 (2004).

on their own, a manufacturer must comply with the 'changes being effected' ('CBE') regulation, set forth at 21 C.F.R. § 314.70(c)(6)(iii). That regulation 'allows drug manufacturers to change [a label] without the FDA's preapproval if the changes "add or strengthen a contraindication, warning, precaution, or adverse reaction," or "add or strengthen an instruction about dosing and administration that is intended to increase the safe usage of the drug product," in order to "reflect *newly acquired information.*"'" (Emphasis added.) *Gibbons v. Bristol-Myers Squibb Co.*, supra, 919 F.3d 707.[18]

The phrase "newly acquired information" is the key component of the CBE regulation. "Because manufacturers may unilaterally update a drug's label if the change complies with the CBE regulation, a state law failure-to-warn claim that depends on newly acquired information – information that Defendants could have added to their label without FDA approval – is not preempted." (Internal citations omitted; internal quotation marks omitted.) Id., 708. That is, "[a]s a general rule ... state law can hold a brand-name manufacturer liable for failing to use its powers under the CBE regulation to add a new warning to a drug label." *Dolin v. GlaxoSmithKline LLC*,

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[18]The actual CBE regulation is lengthy and complex. 21 C.F.R. § 314.70 is entitled: "Supplements and other changes to an approved NDA." Subsection (c) is entitled: "Changes requiring supplement submission at least 30 days prior to distribution of the drug product made using the change (moderate changes)." Paragraph 6 provides: "The agency may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved NDA may commence distribution of the drug product involved upon receipt by the agency of a supplement for the change. These changes include, but are not limited to:" Subparagraph (iii) (A) through (C) then provides as follows: "Changes in the labeling to reflect newly acquired information, except for changes to the information required in § 201.57(a) of this chapter (which must be made under paragraph (b)(2)(v)(C) of this section), to accomplish any of the following: (A) To add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter; (B) To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage;(C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product ...."

supra, 901 F.3d 811. Conversely, if there is no newly acquired information, then the manufacturer is under no duty to change its label and related state failure to warn claims are preempted. See *Utts v. Bristol-Myers Squib Co.,* 251 F. Supp.3d 644, 673 (S.D.NY. 2017) ("the plaintiffs' failure to warn claims are preempted because the information upon which the [plaintiff] relies to plausibly plead these claims does not, upon examination, demonstrate that any newly acquired information exists to support a label change pursuant to CBE regulations.")

Once a manufacturer has submitted the information in question to the FDA, the FDA has some obligation to take action. Section 355 (o) (4) (A) of title 21 provides: "If the Secretary becomes aware of new information, including any new safety information or information related to reduced effectiveness, that the Secretary determines should be included in the labeling of the drug, the Secretary shall promptly notify the responsible person or, if the same drug approved under subsection (b) is not currently marketed, the holder of an approved application under subsection (j)." However, subparagraph (I) of this section provides that "[t]his paragraph shall not be construed to affect the responsibility of the responsible person or the holder of the approved application under subsection (j) to maintain its label in accordance with existing requirements [under the C.F.R.]" 21 U.S.C. § 355 (o) (4) (I).

As stated, a showing that there is no newly acquired information is only one of two ways that a manufacturer can invoke preemption. That is, "[p]ost–FDA approval preemption analysis proceeds in two stages. First, the plaintiff must show that there existed 'newly acquired information' such that the defendants could unilaterally change the label pursuant to the CBE regulation without FDA approval. But, the mere availability of a CBE label amendment does not necessarily defeat a manufacturer's preemption defense. Because the FDA 'retains the authority to

reject labeling changes,' a manufacturer may still—even after the plaintiff has identified 'newly acquired information'—establish an impossibility preemption defense through 'clear evidence that the FDA would not have approved a change' to the label .... In sum, if the plaintiff can point to the existence of 'newly acquired information' to support a labeling change under the CBE regulation, the burden then shifts to the manufacturer to show by 'clear evidence' that the FDA would not have approved the labeling change made on the basis of this newly acquired information." (Internal citations omitted.) *Utts v. Bristol-Myers Squib Co.,* supra, 251 F. Supp.3d 661. Accord *Gibbons v. Bristol-Myers Squibb Co.*, supra, 919 F.3d 708 ("to state a claim for failure-to-warn that is not preempted by the FDCA, a plaintiff must plead a labeling deficiency that [Defendants] could have corrected using the CBE regulation ....If the plaintiff meets that standard, the burden shifts to the party asserting a preemption defense to demonstrate that there is clear evidence that the FDA would not have approved a change to the [prescription drug's] label.") (Citation marks omitted; internal quotation marks omitted.)[19]

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[19]The plaintiff takes issue with this case law and asserts that the defendants should have the burden of proof on the first – or "newly acquired evidence" – part of the analysis because they alleged preemption as an affirmative defense. It is true that the cases cited, unlike the one here, arose on a motion to dismiss rather than as proof of an affirmative defense. Nonetheless, these cases, which assign the initial burden to the plaintiff, did so while still referring to preemption as a "defense," just as it is here. See, e.g., *Gibbons v. Bristol-Myers Squibb Co.*, supra, 919 F.3d 708 ("preemption defense.") Further, at least one Circuit has placed the burden of proof on the plaintiff at trial. See *Dolin v. GlaxoSmithKline LLC*, supra, 901 F.3d 815 (on posttrial motion, "[p]laintiff has failed to offer evidence that [defendant] acquired new information after 2007.") In the present context, a hybrid approach seems in order. On the one hand, it would be virtually impossible for the defendants to prove a negative and negate the existence of newly acquired information without knowing exactly what newly acquired information the plaintiff relies upon. Therefore, it is fair to expect the plaintiff to come forward with the newly acquired information in question. By virtue of their extensive briefing and the presentation of their case to the jury, the plaintiff has done that in this case. From there, the burden can rest on the defendants to prove that the information identified by the plaintiff is not newly acquired. In reality, as the court will discuss, the issue here is a question of law and the

2. The Presence of Newly Acquired Information is a Question of Law

Before delving into the question of what constitutes newly acquired information, the court must address the issue of who decides this question. The court had previously ruled in this case that the issue of preemption was one for the jury to decide. On May 20, 2019, three days after the jury returned a verdict in this case, the United States Supreme Court decided *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). In *Albrecht*, the Court addressed the second prong of preemption which, as discussed, involves the issue of whether there is "clear evidence" that the FDA would not have approved a change to the drug label. The Court defined "clear evidence" to mean evidence showing that the drug manufacturer "fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." Id., 1678. The Court then held that the "question is a legal one for the judge, not a jury." Id., 1679. See also id., 1672 ("We here determine that this question of pre-emption is one for a judge to decide, not a jury.") The Court reasoned that "judges are better suited than are juries to understand and to interpret agency decisions in light of the governing statutory and regulatory context." Id., 1680. The Court added that "sometimes contested brute facts will prove relevant to a court's legal determination about the meaning and effect of an agency's decision." Id. The Court observed: "[W]e consider these factual questions to be subsumed within an already tightly circumscribed legal analysis. And we do not believe that they warrant submission alone or together with the larger pre-emption question to a jury. Rather, in those contexts where we have

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burden of proof is not a determining factor.

determined that the question is 'for the judge and not the jury,' we have also held that courts may have to resolve subsidiary factual disputes that are part and parcel of the broader legal question." (Internal quotation marks omitted.) Id.

Although the issues and analysis on the first prong of the preemption test, involving newly acquired information, are not identical to those involved in the second, clear evidence prong, it seems unlikely that the Supreme Court would hold that the first prong is triable to the jury while the second prong is not.[20] Both prongs involve complicated legal analysis. At this point, neither party in this case argues that the newly acquired information issue should go to the jury. Accordingly, the court will decide the newly acquired information issue as a question of law. Accord *Byrne v. Avery Center for Obstetrics & Gynecology, P.C.*, 314 Conn. 433, 447, 102 A.3d 32 (2014); ("Whether state causes of action are preempted by federal statutes and regulations is a question of law over which our review is plenary.").[21]

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[20]The *Albrecht* Court did not specifically identify the test as being two-pronged, but it acknowledged the concept of "newly acquired information"; id., 1673, 1679; and noted that Merck, the manufacturer of Fosamax, the drug in question, "conceded that the FDA's CBE regulation would have permitted Merck to try to change the label to add a warning before 2010, but Merck asserted that the FDA would have rejected that attempt." Id., 1675. It also "[assumed] ... that ... there is sufficient evidence to find that [the manufacturer] violated state law by failing to add a warning about atypical femoral fractures to the Fosamax label." Id., 1678-79. Thus, there was no need to address the newly acquired information prong any further in that case.

[21]As noted, see note 16 supra, the plaintiff has filed an objection to what he claims is the court's reconsideration of the defendants' summary judgment motion (Entry # 328.00.) The court, however, is not reconsidering the summary judgment motion. Rather, the court is deciding the defendants' postverdict motion for judgment or to set aside the verdict. It is fully appropriate to consider a question of law such as preemption on a postverdict motion, especially when, as here, the grounds for it arose after the jury verdict. See *Hudson United Bank v. Cinnamon Ridge Corp.*, 81 Conn. App. 557, 564 n.9, 845 A.2d 417 (2004) ("[t]he exercise of ... authority [to set aside a verdict] is appropriate where a party could not raise an issue in a motion for a directed verdict during trial because the issue did not arise until after the jury returned its verdict.") The

The plaintiff cites Connecticut case law stating that "[t]here is a strong presumption against federal preemption of state and local legislation." (Internal quotation marks omitted.) *Murphy v. Darien*, 332 Conn. 244, 249, 210 A.3d 56 (2019). That case law comes from cases in which there was a conflict between a federal statute and a state or local statute. See *Dowling v. Slotnik*, 244 Conn. 781, 794, 712 A.2d 396 (1998) (state workers' compensation act). In the present case, the defendants do not seek to invalidate any state statute or section thereof. It is unclear whether the presumption applies in this situation. Further, as will be discussed, the FDA contemplated that the CBE regulation would be used "sparingly." *McGrath v. Bayer HealthCare Pharmaceuticals Inc.*, No. 18CV2134RJDVMS, 2019 WL 2582530, at *5 (E.D.N.Y. June 24, 2019). These competing concerns tend to neutralize each other.

3. What is "Newly Acquired Information"?

To explore the meaning of "newly acquired information," the court starts with the regulatory definition. Federal regulations define "[n]ewly acquired information" as: "[D]ata, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3(b). The cases have added the following gloss. Information previously known to the manufacturer, but not submitted to the FDA, may constitute "newly acquired information," provided that the information meets the other CBE requirements. *Utts v. Bristol-Myers Squib Co.*,

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fact that the court previously found that there were disputed issues of fact for purposes of summary judgment is irrelevant now that the Supreme Court has ruled that the question is primarily one of law for the court and that the court must also resolve any subsidiary fact issues.

supra, 251 F. Supp.3d 659. And, as the regulation suggests, "'Newly acquired information' can include either new data or new analyses of previously submitted data." *Gibbons v. Bristol-Myers Squibb Co.*, supra, 919 F.3d 707. However, any claim that a drug label should be changed based solely on "information previously submitted to the FDA is preempted because the CBE regulation cannot be used to make a label change based on such information." *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Product Liability Litigation*, 185 F. Supp. 3d 761, 769 (D.S.C. 2016). See also *Dolin v. GlaxoSmithKline LLC*, supra, 901 F.3d 816 ("The [2011] article contained the same figures as GSK's 2006 analysis, which GSK submitted to the FDA. There is no basis to conclude that this was a new analysis or that it was 'not previously submitted to the Agency.'")

There is some case law, although not an overwhelming amount, addressing the level, reliability, and quality of information needed to constitute "newly acquired information." "[T]he FDA contemplated that the CBE regulation would be used sparingly, noting it 'would not allow a change to labeling to add a warning in the absence of reasonable evidence of an association between the product and an adverse event.'" *McGrath v. Bayer HealthCare Pharmaceuticals Inc.*, supra, 2019 WL 2582530, at *5.[22] Further, "[t]he FDA has recognized that '[e]xaggeration

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[22]*McGrath* was decided after *Albrecht* and distinguished *Albrecht* as a case arising under the second, "clear evidence" prong of preemption analysis. Id., *5. See also note 20 supra. The *McGrath* court did note, however, with reference to the quality of information necessary to constitute "newly acquired information," that "in *Albrecht*, before the FDA required the drug manufacturer to update its warning, the manufacturer 'performed a statistical analysis of [the drug's] adverse event reports, concluding that these reports revealed a statistically significant incidence of femur fractures' and 'about the same time, [the manufacturer] began to see numerous scholarly articles and case studies documenting possible connections between long-term [drug] use and atypical femoral fractures....' In *Albrecht*, this medical evidence revealed a reasonable, if not compelling, causal association—the kind of causal association the FDA contemplated before a drug company could unilaterally amend a warning under the CBE

of risk, or inclusion of speculative or hypothetical risks, could discourage appropriate use of a beneficial drug ... or decrease the usefulness and accessibility of important information by diluting or obscuring it....' Indeed, 'labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to lose its significance....' For this reason, the CBE regulation requires that there be sufficient evidence of a causal association between the drug and the information sought to be added....[23] Moreover, the FDA retains the authority to reject labeling changes made pursuant to the CBE regulations.... By expressly requiring that a CBE supplement only reflect newly acquired information and 'be based on sufficient evidence of a causal association,' the FDA ensures 'that scientifically accurate information appears in the approved labeling.'" (Citations omitted; footnote added.) *Utts v. Bristol-Myers Squibb Co.*, supra, 251 F. Supp. 3d 659–60.

"The rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments: '[I]f the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement for 'newly acquired information.'" *Wyeth v. Levine*, 555 U.S. 555, 569 (2009) (quoting the Federal Register.)

However, studies published after the plaintiff's injury in the case would not be relevant to

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regulation." (Citation omitted.) *McGrath v. Bayer HealthCare Pharm. Inc.*, supra, 2019 WL 2582530, at *5.

[23]The actual language of the CBE regulation states: "the labeling must be revised to include a warning about a clinically significant hazard as soon as there is *reasonable evidence of a causal association* with a drug; a causal relationship need not have been definitely established." (Emphasis added.) 21 C.F.R. § 201.57 (c) (6) (i).

constitute newly acquired information. See *McGrath v. Bayer HealthCare Pharmaceuticals Inc.*, supra, 2019 WL 2582530, at *2 ("the information was not available in 2015 when Plaintiff was administered Magnevist.") "[I]nconclusive" studies would also "not justify a unilateral label change." Id., at *4. See also id., at *5 ("Studies concluding it 'remains unknown whether GBCAs induce toxic effects' and that 'further studies are required to address possible clinical consequences of gadolinium deposition ... in patients with normal renal function' do not constitute reasonable or well-grounded scientific evidence of 'clinically significant adverse effects' under the CBE regulation.") Similarly, articles that "merely express a desire for further investigation into NOAC dosing regimens or reversal agents" do not constitute newly acquired information. *Utts v. Bristol-Myers Squibb Co.*, supra, 251 F. Supp. 3d 669. "A single study performed on mice does not make a risk 'apparent' or otherwise constitute 'reasonable evidence of an association' between Magnevist and fibrosis." *McGrath v. Bayer HealthCare Pharmaceuticals Inc.*, supra, 2019 WL 2582530, at *5. In sum, new information must have some degree of scientific validity and conclusiveness to constitute "newly acquired information" under the CBE regulation.

B. WAS THERE NEWLY ACQUIRED INFORMATION IN THIS CASE?

1. Blood Plasma Concentrations and Monitoring

The plaintiff's principal claim in this litigation is that various studies and articles show that there is a therapeutic range of Pradaxa blood plasma concentration levels and that doctors should monitor those levels for patients in order to insure that they stay in the therapeutic range, thus minimizing the risk of bleeding events. The defendants argue that these materials do not constitute "newly acquired information" and therefore that federal law preempts the claim.

The court begins with a summary of what the label in effect prior to the time of plaintiff's

bleed – the December, 2013 label – provides with regard to these issues, because information in that label obviously reflects what was "previously included in submissions to FDA" and therefore exempt from the category of newly acquired information under the regulation.[24] Under the heading "Dosing Adjustments," section 2.2 of the 2013 label provides: "[g]enerally, the extent of anticoagulation does not need to be assessed. When necessary, use aPTT or ECT, and not INR, to assess for anticoagulant activity in patients on Pradaxa." (Ex. 94, § 2.2.) Section 10, entitled "Overdosage" adds: "Measurement of aPTT or ECT may help guide therapy." Section 12.2, entitled "Pharmacodynamics" states: "The aPTT test provides an approximation of PRADAXA's anticoagulation effect .... In the RE-LY trial, the median (10th to 90th percentile) trough aPTT in patients receiving the 150 mg dose was 52 (40 to 76) seconds."[25] The next paragraph adds: "The degree of anticoagulant activity can also be assessed by the ecarin clotting time (ECT). This test is a more specific measure of the effect of dabigatran than activated partial thromboplastin time (aPTT). In the RE-LY trial, the median (10th to 90th percentile) trough ECT in patients receiving the 150 mg dose was 63 (44 to 103) seconds." (Ex. 94, § 12.2.)

a. *The Reilly Paper*

In his briefs, the plaintiff cites a number of studies and articles that he claims constitute

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[24]Again, the regulations define "newly acquired information" as: "[D]ata, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3(b).

[25]"Trough" refers to the concentration just before the patient is scheduled to take the next pill. (Ex. 3247, p. 2.)

newly acquired information in this area.[26] The centerpiece of the plaintiff's argument is an article in the Journal of the American College of Cardiology entitled "The Effect of Dabigatran Plasma Concentrations and Patient Characteristics on the Frequency of Ischemic Stroke and Major Bleeding in Atrial Fibrillation Patients." (Ex. 3247 or the "Reilly paper" or "Reilly article") Its principal authors are Paul A. Reilly, PhD, and Thorsten Lehr, PhD, who, at the time, were respectively present and former employees of the defendants. Many of the other authors were also employees or grant recipients of the defendants.

In determining whether this article constitutes newly acquired information, the first issue is timing. Although the article appears in a February 4, 2014 edition of the Journal, the article states that the Journal accepted the manuscript on July 1, 2013. (Ex. 3247, p. 1, footnote.) Because most of the authors are affiliated with the defendants, the defendants can fairly be charged with knowledge of the final contents of the article by July, 2013. Thus, the information in the article was available to the defendants to consider for purposes of a label change under the CBE regulation before the plaintiff's bleed in January, 2014. On the other hand, there is no evidence

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[26]The court relies on the posttrial briefs on the motion for judgment notwithstanding the verdict and to set aside the verdict as the latest and principal source of the parties' positions on the issues. Nonetheless, as noted, the court has reviewed the papers on the summary judgment and directed verdict motions for supplemental guidance and because the parties generally agreed that the court should consider all of the briefs and exhibits cited therein. See note 16 supra. However, the plaintiff, in particular, has submitted numerous supplemental materials, such as a four page chart listing examples of newly acquired information (Pl. Supp. Br. in Opp. to Defs. Motion for Summary Judgment, Entry # 278.00, Ex. Q), an eight page, single spaced document entitled "Preemption Considerations," which was submitted but not marked at oral argument, and a Motion to Supplement the Record, consisting of a ten page memorandum of law and 219 pages of exhibits filed on August 23, 2019 (Entry # 332.00.) These supplemental filings circumvent the court's page limitations, unfairly create uncertainty for the defendants as to how to respond, and pose an undue burden on the court in its attempt to finalize a decision. Out of an abundance of caution, however, the court has considered these materials as well.

that the defendants submitted the article to the FDA until sometime in 2014, presumably after the plaintiff's bleed.[27] Thus, the defendants cannot rely on the contention that the Reilly article was "previously included in submissions to FDA" under the regulation.

Therefore, the court turns to the merits of whether the article contains newly acquired information. The article states at the outset that "[c]urrently it is unknown whether there is a single concentration range where the balance between thromboembolic events [strokes] and bleeding events is optimal for all AF [atrial fibrillation] patients." (Ex. 3247, p. 2.) The next paragraph ends the introduction to the article: "The rates of stroke and major bleeding in DE-treated patients[28] have been investigated across a variety of patient subgroups ... but correlations of stroke and bleeding risk with individual plasma concentrations have not been presented. The aims of this pharmacokinetic (PK) analysis of the RE-LY trial were to explore the association between plasma concentrations and efficacy and safety outcomes, and to identify factors affecting the variability of plasma concentrations of dabigatran and their impact on outcome events in AF patients with an indication for oral anticoagulants." (Footnote added.) (Ex. 3247, p. 2.) After a thorough discussion and analysis, the article concludes as follows: "Both doses of DE in RE-LY

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[27]In the following excerpt from the May, 2019 trial, defense counsel asked Dr. Plunkett a question that assumes that the defendants submitted the Reilly paper five years earlier, which would have been in mid-2014.
Q "In the five years since the company has submitted the Reilly paper through this PSUR to the FDA, there's no point in time, you can point me to, where the FDA has said based on the data and the Reilly paper, we think there should be blood testing with Pradaxa, blood monitoring?
A "That is correct. But the update has also not been provided some of the interpretations that the company originally had, either."
(5/13/19 p.m. Tr., p. 28.)

[28]"DE" refers to dabigatran exiletate, the chemical name for Pradaxa.

were associated with a more than 5-fold variation in plasma concentrations, indicating a wide therapeutic range. Renal function was the predominant patient characteristic that determined plasma concentrations. Safety and efficacy outcomes were correlated with plasma concentrations of dabigatran, with age as the most important covariate. There is no single plasma concentration range that provides optimal benefit–risk for all patients. The balance between stroke risk and bleed risk varied with concentration, suggesting that there is a subset of AF patients who may improve their benefit–risk balance with DE by a tailoring of the dose in relation to patient characteristics." (Ex. 3247, p. 8.)[29]

There is no dispute that the Reilly paper constitutes a work of sufficient reliability or substance to qualify under the definition of newly acquired information. That definition includes "[D]ata, analyses, or other information not previously submitted to the [FDA], which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data e.g., meta-analyses." It is true that the article does not rely on new "data" or "new clinical studies." Instead the article analyzes data from the RE-LY trial that the defendants submitted to the FDA prior to the initial approval. The article thus consists of a "new analysis of previously submitted data."[30]

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[29]The version of the Reilly article submitted at trial contained redactions to eliminate references to the 110 mg dose, which the FDA did not approve. (Ex. 94, § 6.1.) As a result of the FDA action, the court ruled that any claim that the defendants should have advised doctors to consider the 110 mg dose was preempted in this case. (Entry # 283.00, pp. 3-4.) The court quotes from the unredacted version, which is found in Exhibit C to plaintiff's supplemental brief in opposition to the defendants' motion for summary judgment on the basis of federal preemption. (Entry # 278.00)

[30] Dr. Plunkett testified as follows:
Q "And I asked you this a moment ago, but as part of the approval process, Boehringer submitted all of that blood concentration data from the RE-LY study to the FDA?

The issue then becomes whether this new analysis reveals "risks of a different type or greater severity or frequency than previously included in submissions to FDA." The plaintiff relies on various emails, documents, comments, and discussions concerning potential therapeutic ranges in early drafts of the Reilly paper. (Pl. Br., pp. 21-22.) For example, the plaintiff quotes Reilly's own email in which he states "Of course I am aware that the conclusions that appear to emerge from this paper are not the ones currently wished for by marketing (that dose adjustment will optimize therapy), let's just see where this paper ends up." (Pl. Br., p. 22; Ex. 5.)[31] These preliminary discussions do not provide reliable evidence of new risks. They are essentially uncorroborated trial balloons. To be sure, it is fully appropriate for a scientific dialogue to take place, and disagreement to occur, during the drafting of a major paper. There is no reason to believe that the process of drafting and finalizing a scientific paper does not benefit from the same type of advocacy, examination, and argument that is the hallmark of our own judicial system. In both cases, the decision is better because the opposition was heard. But, ultimately, a preliminary opinion or dissenting voice is just that – it is not a final opinion.

The text of the actual published article does contain a few statements suggesting a

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A "Yes. All of the individual patient data was submitted to the FDA.
Q "Boehringer did their own analyses of it. Right?
A "Yes, they did.
Q "And the FDA did their own analyses on it. Correct?
A "They did some analyses, yes."
(5/13/19 a.m. Tr., p. 104.)

[31]The plaintiff's brief includes the parenthetical phrase "(that dose adjustment will optimize therapy)," which is redacted in Exhibit 5. The court assumes that the plaintiff has correctly quoted the unredacted version.

correlation between plasma levels and bleed risk. The article states "Across the 10th to 90th percentile range of steady-state trough plasma concentrations achieved for the 150-mg bid [twice a day] dose, the overall risk of major bleeding during the trial ranges from approximately 2% to 7% (approximately 1.0% to 3.5% per year) ...." (Ex. 3247, p.7) and, in the conclusion, that "[s]afety and efficacy outcomes were correlated with plasma concentrations of dabigatran ...." (Ex. 3247, p.8.) However, the FDA was well aware of this correlation. In the FDA's September, 2010 Clinical Pharmacology Review of Pradaxa, issued just prior to Pradaxa's launch, the FDA reported the following based on the RE-LY trial: "There is a significant relationship between dabigatran exposures and incidence of bleeding events (major bleeding or life-threatening bleeding). The probability of a life-threatening bleed, defined as fatal bleeding, symptomatic intracranial bleeding, bleeding associated with a reduction in hemoglobin levels of at least 50 g/l or leading to a transfusion of at least 4 units of blood or packed cells or bleeding necessitating surgical intervention, increases with increasing dabigatran concentration. Going from the 10^{th} to 90^{th} percentile of observed pre-dose dabigatran concentrations (22.9 ng/mL to 238.3 ng/mL) in RE-LY, the probability of a life-threatening bleed within 1 year in a typical patient is predicted to increase from 0.27% to 1.82 %." (Ex. 5813, p. 10.) The Review includes a graph clearly depicting the increased risk of bleeding as dabigatran concentration levels rise to the 90^{th} percentile and above. (Ex. 5813, p. 62.) Given that the FDA already knew of the association between high Pradaxa blood plasma concentrations and bleeds (and nonetheless did not require the defendants specifically to warn of it in the label), the Reilly paper's reference to that

association does not constitute a new analysis or newly acquired information.[32]

Therefore, the court looks to the ultimate conclusion of the article. Bearing in mind that the purpose of the article was to "explore the association between plasma concentrations and efficacy and safety outcomes," it is fair to say that the ultimate conclusion was that "[t]here is no single plasma concentration range that provides optimal benefit–risk for all patients." The conclusion mentions other risk factors such as renal function and age, but the U.S. label at the time fully disclosed these risks. (Ex. 94, §§ 2.1, 2.2., 5.2, 8.5, 8.6, 12.3.) The conclusion also states that "[t]he balance between stroke risk and bleed risk varied with concentration, suggesting that there is a subset of AF patients who may improve their benefit–risk balance with DE by a tailoring of the dose in relation to patient characteristics." But the label already advises of the availability of a 75 mg dose for patients with severe renal impairment, and the FDA did not approve the 110 mg dose. (Ex. 94, §§ 2.1, 6.1.)

Given, then, that the only relevant part of the conclusion is that "[t]here is no single plasma concentration range that provides optimal benefit–risk for all patients," it necessarily follows that the article does not establish any "risks of a different type or greater severity or frequency than previously included in submissions to FDA." Indeed, the article essentially concludes that it is not possible to identify a group of patients with specific concentrations of Pradaxa in their blood plasma who are at an unacceptable risk of bleeding relative to the need to

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[32]Although the Reilly paper reports slightly higher one year bleed rates than does the FDA (1 to 3.5% versus 0.27% to 1.82%), the Reilly paper reported on "major" bleeds whereas the FDA's statistics refer to "life-threatening" bleeds. The FDA passage quoted above reveals that there is a difference between the two types of bleeds. The main point, as stated above, is that the FDA already had information that there is an increasing risk of bleeding as Pradaxa blood concentration levels rise.

reduce the risk of stroke. Because the Reilly paper does not identify any specific plasma concentration levels that pose "risks of a different type or greater severity or frequency than previously included in submissions to FDA," the Reilly paper does not constitute newly acquired information.[33]

b. *Clinical Overview Statement*

The plaintiff's brief next points to the defendants' July, 2011 Clinical Overview Statement. In a section entitled "Trough Plasma Concentration" based on data from the RE-LY trial, the statement reports: "The 90th percentile of trough plasma concentration after 150 mg BID [twice a day] was 215 ng/mL ... The European SmPC [or European label] will refer to 200 ng/mL to be associated with an increased risk of bleeding: "*...dabigatran concentrations above 200 ng/ml, measured at trough after 150 mg twice daily dosing (10-16 hours after the previous dose), are associated with an increased risk of bleeding.*'" (Italics in original.) (Ex. 149, p. 4.)

There is no dispute that the defendants did not submit this document to the FDA. For several other reasons, however, this statement does not constitute newly acquired information. First, it is arguable whether the statement in question constitutes "[D]ata, analyses, or other information" within the meaning of the CBE regulation. The passage appears to be merely a recitation of what the defendants will include in the European label, presumably in order to comply with European requirements.

Perhaps more importantly, even though the defendants did not submit the Clinical

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[33]For all these reasons, the court respectfully disagrees with the conclusion of the United States District Court for the Southern District of West Virginia that the Reilly paper constitutes newly acquired information. See *Knight v. Boehringer Ingelheim Pharmaceuticals, Inc.*, No. CV 3:15-6424, 2019 WL 2144812, at *4 (S.D.W. Va. May 15, 2019).

Overview Statement to the FDA, the FDA was already well aware of the association between high blood plasma concentrations of Pradaxa and the increased risk of bleeding. As discussed, the 2010 FDA Clinical Pharmacology Review states: "There is a significant relationship between dabigatran exposures and incidence of bleeding events (major bleeding or life-threatening bleeding). The probability of a life-threatening bleed ... increases with increasing dabigatran concentration. Going from the 10th to 90th percentile of observed pre-dose dabigatran concentrations (22.9 ng/mL to 238.3 ng/mL) in RE-LY, the probability of a life-threatening bleed within 1 year in a typical patient is predicted to increase from 0.27% to 1.82 %." (Ex. 5813, p. 10.) As also stated, a graph clearly depicts this trend. (Ex. 5813, p. 62.) Thus, in effect, the information was "previously submitted to the [FDA]."

Moreover, the 2013 U.S. label contains additional information that reveals the FDA's understanding of the association between high Pradaxa concentration levels and bleeds. As noted earlier, the U.S. label states that: "[m]easurement of aPTT or ECT may help guide therapy." The label then provides the median trough concentration levels from the RE-LY trial for the 10th to 90th percentiles using the aPTT and ECT tests.[34]

Finally, the premise and conclusion of the Reilly article, discussed above, are also important here. The premise of the article, which became finalized in July, 2013, was that "[c]urrently it is unknown whether there is a single concentration range where the balance between thromboembolic events and bleeding events is optimal for all AF patients." (Ex. 3247, p.

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[34]There was testimony that the aPTT and ECT tests represent "ways to measure plasma concentration" and that they are essentially a "proxy" for determining plasma concentration levels. (Ct. Ex. 8 (testimony of Dr. Siegfried Eberle), pp. 10-11.) As mentioned, the label also identifies the aPTT and ECT tests as "an approximation of PRADAXA's anticoagulation effect." (Ex. 94, § 12.2.)

2.) The conclusion was that "[t]here is no single plasma concentration range that provides optimal benefit–risk for all patients." (Ex. 3247, p. 8.) These statements refute both the basis or need for a warning in the United States that blood plasma concentrations above a specific level pose additional dangers for all patients. For all these reasons, the blood concentration data in the Clinical Overview Statement does not reveal "risks of a different type or greater severity or frequency than previously included in submissions to FDA." Accordingly, the Clinical Overview Statement does not constitute newly acquired information. See *Dolin v. Glaxosmithkline, LLC,* supra, 901 F.3d 816 ("There is no basis to conclude that this [article] was a new analysis or that it was not "previously submitted to the Agency.'")[35]

c. *Blood Monitoring*

A central thesis of plaintiff's case is that Pradaxa's label is deficient because it does not recommend monitoring of a patient's blood levels to determine whether there are excessive concentrations of Pradaxa in the blood plasma or other evidence of overanticoagulation. As stated, the 2013 Pradaxa label does provide that "[m]easurement of aPTT or ECT may help guide

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[35]The defendants also contend that they can satisfy the second or alternate basis for preemption on this issue and show that there is "clear evidence" that the FDA rejected a label change warning about excessive Pradaxa exposure. (Def. Br., p. 19 n.14.) As stated, the Supreme Court defined "clear evidence" to mean evidence showing that the drug manufacturer "fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Merck Sharp & Dohme Corp. v. Albrecht*, supra, 139 S. Ct. 1678. In October, 2010, the defendants submitted to the FDA a proposed warning that "[a]n aPTT greater than 80 sec is associated with higher risk of bleeding." (Exs. 5054, 5056, § 5.1.) The FDA struck that language from the defendants' proposed label. (Ex. 5036, § 5.1.) However, the shortcomings in the defendants' proof are: 1) it is not clear that the defendants "fully informed the FDA of the justifications for the warning required by state law" and 2) the proposed language follows a sentence that begins with the phrase "[i]n patients who are bleeding ...." and it is not clear whether the proposed language is limited to that class of patients. For these reasons, the court finds that the defendants did not satisfy the alternate basis for preemption on this issue.

therapy." The question is whether there was any newly acquired information that would allow for a stronger warning to doctors of a need to monitor blood levels.

The plaintiff's briefs do not identify a single published article or even statement in a scientific journal that recommends regular blood monitoring. The plaintiff's expert, Laura Plunkett, testified in favor of blood monitoring, but the court is unaware of any authority for the proposition that expert testimony at trial, unsupported by any published research, can constitute newly acquired information. In fact, Plunkett confirmed that there were no "professional societies of doctors who have issued guidelines recommending the kind of monitoring that [she proposes.]" (5/3/19 p.m. Tr., p. 60.)

On the other hand, there is at least one leading article that recommends against monitoring. The article, published in the May, 2018 American Heart Journal, is entitled "Is there a role for pharmacokinetic [PK]/pharmacodynamic [PD]-guided dosing for novel oral anticoagulants?" Commonly referred to as the "Chan article," the lead author is Dr. Noel Chan; the other authors include Dr. Reilly of the defendants and four FDA scientists. The article concludes: "[r]outine PK-PD measurements to guide NOAC dosing cannot currently be recommended because of the lack of reliable tests, lack of clinical evidence of benefit, and lack of data to guide appropriate dosing." (Ex. 6085, p. 8; Defendants' motion for summary judgment (Entry # 130.00), Ex. 31, p. 66.) Thus, the only published article cited on the issue of monitoring essentially concludes that it is not a reliable way of determining blood levels and that the absence of monitoring does not pose greater risks for patients. Under these circumstances, the court cannot conclude that there is any

newly acquired information concerning blood monitoring.[36]

d. *Other Articles and Studies*

The plaintiff cites a number of other articles from medical journals and studies to support his contention that there is newly acquired information concerning blood concentration or blood monitoring. After review, the court concludes that these articles do not state any relevant newly acquired information.

i. Eikelboom article. From a 2011 article by John W. Eikelboom and others from the journal Circulation, the plaintiff highlights the following language: "However, we have not reported previously the safety results of both doses of dabigatran compared with warfarin for different types of major bleeding and in key subgroups....To provide more detail for this analysis, the adjudication documents for all major bleeding events of unknown site were reviewed by 2 adjudicators, and, when possible, bleeding events were classified according to site of bleeding. Adjudication documents for all major gastrointestinal bleeding events were also reviewed, and, when possible, gastrointestinal bleeding events were classified according to whether they were from the upper or lower gastrointestinal tract." (Ex. 3124, pp. 1-2; Pl. Br., p. 23.) This language does little more than describe methods used in the study. The conclusion of the article states: "In patients with atrial fibrillation at risk for stroke, both doses of dabigatran compared with warfarin

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[36]Even though the article was published in 2018, well after the plaintiff's bleed in 2014, the court considers the article because it tends to show that there was also no newly acquired information on monitoring at any time up to 2018, including the period prior to 2014. Such a look forward is not in conflict with the proposition, cited earlier and discussed below, that an article identifying newly acquired information for the first time, but published after the patient's injury, cannot constitute newly acquired information under the CBE regulation. In that instance, there is no basis for a label change because the manufacturer would not have been able to change the label in time to prevent the injury.

have lower risks of both intracranial and extracranial bleeding in patients aged < 75 years. In those aged ≥75 years, intracranial bleeding risk is lower but extracranial bleeding risk is similar or higher with both doses of dabigatran compared with warfarin." (Ex. 3124, p. 1.) This conclusion is irrelevant to the present case, which does not involve a cranial bleed. In any event, the Pradaxa label reports on the relative risks of intracranial hemorrhage and identifies age as a general risk factor. (Ex. 94, Table 2, § 8.5.) Hence the article contains no relevant newly acquired information.

ii. Bytzer article. The plaintiff next cites an article written by Peter Bytzer and several consultants for the defendants in the March, 2013 journal "Clinical Gastroenterology and Heptalogy." The article is entitled: "Analysis of Upper Gastrointestinal Adverse Events Among Patients Given Dabigatran in the RE-LY Trial." The plaintiff italicizes the following language: "In the present study, we analyzed the RE-LY database to describe the clinical characteristics of dabigatran-related nonbleeding upper gastrointestinal adverse events (NB-UGI-AEs)." (Ex. 3330, p. 2; Pl. Br., p. 22.) Again, the highlighted language merely describes the study without identifying any relevant newly acquired information. The conclusion contained in the abstract states: "Among patients given dabigatran for atrial fibrillation, NB-UGI AEs are generally mild or moderate; 4% stopped taking the drug over a median of 21.7 months. The greatest increase was in GERD-type NB-UGI AEs. These observations should guide management and prevention strategies." (Ex. 3330, p. 1.) The conclusion thus discloses nothing of consequence with regard to blood concentration or monitoring.[37]

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[37]The only note of warning in this conclusion is the suggestion that Pradaxa use may cause GERD conditions as an adverse reaction. As mentioned, the Pradaxa label already discloses GERD as a possible adverse reaction. (Ex. 94, § 6.1.) The GERD preemption issue is

iii. Desai article. The plaintiff quotes from an article in "Thrombosis and Hematosis" written principally by Jay Desai and entitled "Gastrointestinal bleeding with the new oral anticoagulants – defining the issues and the management strategies." The only language of consequence highlighted by the plaintiff states: "In patients receiving dabigatran ... laboratory studies of coagulation function will provide useful qualitative information related to the extent of anticoagulation, and therefore the PT, aPTT, and (where available) thrombin time should be obtained ...." (Ex. 3333, p. 5; Pl. Br., p. 23.) This passage, however, comes in a paragraph that addresses the "patient taking NOACs who develops clinically overt or major GI bleeding ..." and goes on to address proper management of this acute type of patient. It does not recommend routine monitoring of otherwise healthy Pradaxa patients for excessive plasma concentrations. The passage quoted is essentially equivalent to the language already in the label in 2013 providing "When necessary, use aPTT or ECT, and not INR, to assess for anticoagulant activity in patients on PRADAXA." (Ex. 94, §2.2.) Therefore, this article does not constitute newly acquired information.

iv. BI studies. The plaintiff identifies a study and model drafted by the defendants in 2012 that suggest a basis for measurement of Pradaxa blood concentration levels. (Pl. Supp. Br. in Opp. to Defs. Motion for Summary Judgment, Entry # 278.00, Exs. A, B.) A review of these items reveals that they are preliminary in nature and examine only potential strategies. (Ex. A: "Potential Mid to Long Term Strategy for Pradaxa in SPAF.") (Ex. B, p. 3: "Model-based evaluation whether further improvement of the safety and efficacy outcomes in SPAF patients

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the different one of whether, in Pradaxa patients, GERD is a risk factor for bleeding.

may be possible by dosing based on exposure"). Such preliminary studies do not constitute newly acquired information. See *Utts v. Bristol-Myers Squibb Co.*, supra, 251 F. Supp. 3d 669.

v. BI's "Supplement for High Bleeding Risk." The plaintiff's post-argument Motion to Supplement the Record does not mention any specific newly acquired information but rather makes the unremarkable and undisputed point that post-approval analyses of the RE-LY data can constitute newly acquired information that can support a CBE label change. (Entry #332.00.) Nevertheless, the court's independent review of the attached exhibits reveals a BI paper entitled "Supplement for High Bleeding Risk." This paper contains the statement that "There may be individual patients where the bleeding risk outweighs the stroke risk. In such cases, a dose of DE110 may be preferred." (Entry #332.00, Ex. E., p. 8, to Ex. 2.) Given the FDA's rejection of the 110 mg dose, this statement does not reveal a new risk concerning, or a new reason to discontinue, the 150 mg dose. Further, another document that BI submitted to the FDA during the relevant time period, which is entitled "Labeling History" and which contains proposed labeling, relies on the "Overview statement for high bleeding risk" as a reference. (Entry #332.00, Ex. D, p. 3, to Ex. 2.) Thus, the information in these documents was previously submitted to the FDA. For these reasons, the statement does not represent newly acquired information.

vi. Post-bleed articles. The plaintiff cites a 2016 article by Kalil and a 2018 article by Kolb. (Exs. 3344, 3360.) These articles postdate the plaintiff's bleed and obviously could not have provided the basis for a label change that might have prevented that bleed. See *McGrath v. Bayer HealthCare Pharmaceuticals Inc.*, supra, 2019 WL 2582530, at *2.[38] Further, the point of

[38]The same is true of the article, cited by the plaintiff in an earlier brief, by Lauffenburger entitled "Predictors of Gastrointestinal Bleeding Among Patients with Atrial Fibrillation After Initiating Dabigatran Therapy," in the November, 2015 edition of Pharmacotherapy. (Pl. Supp.

the passages highlighted by the plaintiff – that Pradaxa caused higher rates of gastrointestinal bleeding than warfarin (Coumadin) – was fully disclosed in the 2013 U.S. label. (Ex. 94, § 6.1: "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 ...) and a higher rate of any gastrointestinal bleeds (6.1% vs. 4.0%, respectively.))" Thus, these articles do not contain any newly acquired information, much less information acquired in time for a label change that could have affected this case.

In sum, after review of the numerous articles and reports identified by the parties in their briefs, the court concludes that there was no newly acquired information that would have allowed the defendants to make a label change on their own on the topics of Pradaxa blood concentration levels or blood monitoring. Accordingly, the court finds these claims preempted.

B. GERD

The issue of whether there was newly acquired information about GERD is critical in this case because, as shown, the claim that the warnings about GERD were inadequate was the only claim for which there was sufficient evidence to prove causation in fact. For the GERD claim, the plaintiff relies solely on portions of Exhibit 80, which is entitled "Summary of Product Characteristics" and occasionally abbreviated as "SmPC," but which the parties commonly recognize as the European label for Pradaxa.

There is no dispute that different standards govern approval and labeling of Pradaxa in Europe and the United States. The European Medicines Agency (EMA) has approved a 110 mg dose of Pradaxa and the European label is 162 pages. (Ex. 80.) In contrast, the FDA did not

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Br. in Opp. to Defs. Motion for Summary Judgment, Entry # 278.00, p. 7.)

approve the 110 mg dose and the U.S. label is approximately sixteen pages. (Ex. 5881, § 1.) The U.S. label is supposed to be as concise as possible. (5/3/19 Tr., p. 37.) Nonetheless, despite the differing labeling standards, it is possible that a foreign label may contain information that qualifies as newly acquired information under our country's CBE regulation and that would be permissible to include in the U.S. label.

Exhibit 80 states a "[d]ate of first authorisation [sic]" as August 1, 2011 and a "date of latest renewal" of January 17, 2013, both of which fall within the relevant time period between October, 2010, when the FDA first approved Pradaxa, and January, 2014, when the plaintiff suffered his bleed. Page 60 of the European label contains the following statement: "For subjects with gastritis, esophagitis, or gastroesophageal reflux the dose of 220 mg taken as one 110 mg capsule twice daily may be considered due to the elevated risk of major gastrointestinal bleeding ...." Page 63 states: "This increased risk [of major gastrointestinal bleeding] was seen in ... the presence of ... gastroesophageal reflux ...."[39] Page 64 contains a chart that summarizes "factors which may increase haemorrhagic risk." In the category of "Diseases/procedures with special haemorrhagic risks" the following are listed: "Esophagitis, gastritis or gastroesophageal reflux."

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[39]The complete paragraph, without redactions made at trial, provides as follows: "In a study of prevention of stroke and SEE [systemic embolic events] in adult patients with NVAF [nonvalvular atrial fibrillation], dabigatran etexilate was associated with higher rates of major gastrointestinal (GI) bleeding which was statistically significant for dabigatran etexilate 150 mg twice daily. This increased risk was seen in the elderly (≥ 75 years). Use of acetylsalicylic acid (ASA), clopidogrel or non steroidal antiinflammatory drug (NSAID), as well as the presence of esophagitis, gastritis or gastroesophageal reflux requiring increase the risk of GI bleeding. In these atrial fibrillation patients a dosage of 220 mg dabigatran given as 110 mg capsule twice daily should be considered and posology recommendations in section 4.2 be followed. The administration of a PPI can be considered to prevent GI bleeding." (Ex. 80, p. 63.) It is apparent that the third sentence contains a grammatical error centering around the word "requiring." In the text above, the court has attempted to quote an excerpt from this paragraph that fairly states its intended meaning.

The label adds on page 64 that "[t]he presence of ... conditions ... which significantly increase the risk of major bleeding requires a careful benefit-risk assessment." (Ex. 80.)

The initial question is whether this information falls into the category of "[D]ata, analyses, or other information ..., which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses)." This question presents a close call. The passages do not present new data. Rather, the data apparently came from the RE-LY trial. (Ex. 80, p. 63 (referring to "a study of prevention of stroke and SEE [systemic embolic events] in adult patients with NVAF"; cf. Ex. 94, § 14 (The primary objective of this [RE-LY] study was to determine if PRADAXA was non-inferior to warfarin in reducing the occurrence of the composite endpoint, stroke (ischemic and hemorrhagic) and systemic embolism.")) However, as discussed, "'[n]ewly acquired information' can include either new data or new analyses of previously submitted data." *Gibbons v. Bristol-Myers Squibb Co.*, supra, 919 F.3d 707. The passages from the European label do not constitute a lengthy analysis, but they repeat over several pages a clear message based on data that, for patients with a history of GERD, there is an "elevated risk of major gastrointestinal bleeding." In view of the fact that the statements come from the defendants themselves, it is clear that the defendants fully credit the statements and it is perhaps not necessary for the defendants to elaborate on their reasoning. Further, the CBE regulation is not strictly limited to analyses but encompasses "data, analyses, or *other information.*" (Emphasis added.) At the very least, the European label contains information about GERD that meets a threshold level of reliability and detail.

The next question is whether this information reveals "risks of a different type or greater

severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3(b). At the outset, the defendants suggest that this information was contained in the original Pradaxa label, which the defendants drafted and submitted to the FDA, and was therefore "previously included in submissions to FDA" prior to its publication in Europe. Contrary to the defendants' suggestion, the court finds that the original Pradaxa label did not disclose this information. The defendants point to language under the heading "Gastrointestinal Adverse Reactions" in § 6.1 of the label stating: "Patients on PRADAXA 150 mg had an increased incidence of gastrointestinal reactions (35% vs. 24% on warfarin). These were commonly dsypesia ... and gastritis-like symptoms (including GERD ....)" (Ex. 5881, § 6.1.) This language discloses that GERD is a possible adverse reaction of taking Pradaxa and not, as stated in the European label, the almost opposite proposition that, in patients with a history of GERD, bleeding is a possible adverse reaction of taking Pradaxa. Similarly, language in § 17.3 of the original label discloses GERD as an adverse reaction to Pradaxa, rather than disclosing bleeding as a reaction for GERD patients.[40] In short, the European label discloses for the first time that, for patients with a history of GERD, there is an "elevated risk of major gastrointestinal bleeding" and "special haemorrhagic risks." Thus, the European label discloses a risk of either a "different type" or of "greater ... frequency" than the original U.S. label.[41]

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[40]Section 17.3 is entitled "Gastrointestinal Adverse Reactions" and instructs doctors to have their patients "call their health care provider if they experience any signs or symptoms of dyspepsia or gastritis: ... epigastric discomfort, GERD (gastric indigestion)." (Ex. 5881.)

[41]An argument exists that the GERD information does not disclose a risk of a "different type" than contained in the original label because the risk it reveals is a risk of bleeding, which was already comprehensively disclosed in that label. (Ex. 5881, "Warnings and Precautions," § 5.1, Medication Guide, p. 1.) As far as can be determined, no court has addressed the issue raised here of what level of inquiry is required to determine whether there is a risk of a "different type."

The court must next examine whether this new information in the European label was "not previously submitted to the FDA" relative to the plaintiff's injury.[42] As discussed, if the article was submitted in a timely fashion, then the information does not qualify as "newly acquired information" and the GERD claim would be preempted. See *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Product Liability Litigation*, supra, 185 F. Supp. 3d 769.

The plaintiff contends initially that merely transmitting the new information to the FDA is not enough and that the defendants must also expressly request a label change. The court does not accept this contention. First, the regulation itself does not require a specific request for a label change but merely refers to information "not previously submitted to the [FDA]." Second, one can assume that the FDA, as a public agency, will "properly [discharge] [its] official duties" and request a label change if the circumstances warrant. See *Merck Sharp & Dohme Corp. v. Albrecht*, supra, 139 S. Ct. 1684 (Alito, J., concurring in the judgment) (citing *United States v. Chemical Foundation, Inc.*, 272 U.S. 1, 14-15 (1926)). Indeed, as mentioned, the FDA has a statutory obligation to do so. See 21 U.S.C. § 355 (o) (4) (A). Third, the defendants cannot be faulted if they exercise caution in submitting a study to the FDA even though they are not sure

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In any event, even if the GERD information does not qualify as a risk of a different type, it arguably discloses a risk of "greater ... frequency" than previously revealed because it identifies an additional subpopulation that has an increased risk of bleeding.

[42]Again, the regulation defines "newly acquired information" as "[D]ata, analyses, or other information *not previously submitted to the [FDA]*, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3(b). The italicized language refers to the same concept as the language "previously included in submissions to FDA" found at the end of the regulation. They are phrased somewhat differently because of their position in the sentence. The court uses the italicized version of the language for the discussion that follows for purposes of clarity.

whether it merits a labeling change. Contrary to the plaintiff's argument, there is no evidence, at least in this case, of what the plaintiff predicted would be a "document dump," whereby the defendants would merely send everything to the FDA in order to escape their responsibilities under the CBE regulation. (7/17/19 Tr., p. 62.)[43]

Nevertheless, the record in this case of whether the defendants submitted the European label to the FDA prior to the plaintiff's bleed is unclear. Laura Plunkett, plaintiff's expert, testified specifically that the defendants "regularly submitted" the European label, or SMPC, as part of their periodic safety update reports (PSURs).[44] Plaintiff's counsel confirmed that the defendants at least "transmitted" the European label to the FDA as part of their "periodic update report."[45]

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[43]In fact, the plaintiff has also criticized the defendants for not submitting enough materials to the FDA. (Pl. Mem. in Opp. to Defs. Motion for Summary Judgment, # 145.00, p. 5.)

[44]Q "It's true, is it not, that Boehringer regularly submitted the CCDS and the SMPC [European label] to the FDA?
A. "As part of a submission of their PSURs [periodic safety update report], they did, yes.
Q "And those PSURs specifically flagged what's changed in those documents from time to time. Correct?
A "Yes."
(5/3/19 a.m. Tr., p. 35.)

[45]THE COURT: "-- but do you agree that this document itself was submitted -- at least submitted to the FDA?
ATTY. MOSKOW: "Which document, Your Honor?
THE COURT: "Exhibit 80.
ATTY. MOSKOW: "I believe as part of a periodic update report on all foreign [labeling] is submitted. So the actual -- I should say it's transmitted, not submitted. And I think that's the

However, the only PSUR in the record is dated May, 2014 – four months after the plaintiff's bleed. (Ex. 6062A, p.2.) Thus, it appears that this report was "not previously submitted to the [FDA]."[46] Further, an examination of this PSUR reveals that it does not contain the information in the European label about GERD.[47] On this record, therefore, the court cannot conclude that the GERD information was previously submitted to the FDA.

The defendants nonetheless assert a form of harmless error argument to the effect that submission of data to the FDA, even after the injury in question, followed by FDA inaction demonstrates that the FDA would have rejected a proposed labeling change even if the company had submitted the information in time for a label change prior to the injury. There is admittedly some logic to this argument. See *Merck Sharp & Dohme Corp. v. Albrecht*, supra, 139 S. Ct. 1684 (Alito, J., concurring in the judgment) ("if the FDA declines to require a label change despite having received and considered information regarding a new risk, the logical conclusion is that the FDA determined that a label change was unjustified.") The difficulties with this argument in this case are two-fold. First, as a factual matter, it is unclear on this record that the defendants ever submitted the European label language to the FDA, even after the bleed. Second, as a legal matter, the defendants' argument amounts to a second prong "clear evidence" claim without the "clear evidence" that the Supreme Court now requires. Again, the Court now defines "clear

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significant difference in language judge."
(7/17/19 Tr., pp. 61-62.)

[46]The 2014 report contains a reference to what is apparently a 2013 report. (Ex. 6062A, p. 5 ("the last PSUR [U13-2574-01], was distributed by 11 Sep 2013 ....")) But the 2013 report is not in the record.

[47]The defendants submitted 314 pages of the report. However, the report itself indicates that it is 635 pages long.

evidence" as evidence showing that the manufacture "fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." Id., 1678. In the present case, it is not clear that the defendants "fully informed the FDA of the justifications for the [GERD] warning required by state law ...." or that the FDA actually "informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." In the absence of these express statements, the defendants cannot satisfy the "clear evidence" prong of the preemption test.

In sum, the court finds that the statements in the European label about GERD qualify as "new analysis or other information" of sufficient reliability and detail, that they reveal a risk of either a "different type" or of "greater ... frequency" than the original U.S. label, and that, on this record, the information was "not previously submitted to the FDA." Accordingly, the court concludes that the plaintiff's GERD claim is not preempted.[48]

III. DEFENDANTS' MOTION FOR NEW TRIAL

A. THE DEFENDANTS' CLAIM THAT THE COURT IMPROPERLY EXCLUDED EVIDENCE CONCERNING BLOOD MONITORING

The defendants claim that a number of trial errors warrant setting aside the verdict and granting a new trial. In the defendants' Motion in Limine #1, the defendants asked the court to "preclude Plaintiff from offering any evidence, testimony, or argument regarding the 110 mg dose

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[48]Thus, in this case, the federal CBE regulation allowed the defendants to include GERD warnings in the U.S. label. The plaintiff still has the burden to show, under state law, that the defendants breached a duty to include the warnings or that the warnings included were inadequate. As discussed above, the plaintiff met that burden in this case.

of Pradaxa, which is approved for stroke prevention in atrial fibrillation only outside of the United States." (Entry # 194.00, p.1.) The court ruled somewhat less expansively that it "will not allow the plaintiff to elicit evidence that the defendants or the Pradaxa label should warn doctors that the '150 mg. dose' is 'too much' or 'inappropriate,'or words to that effect, because such evidence tends to suggest that another dose was appropriate, which the FDA has ruled against. However, the plaintiff may elicit evidence that the label should warn that, under some circumstances, *Pradaxa* is inappropriate or that the doctor should switch therapies, because such a warning does not implicate the dosage issue." (Entry # 283.00, pp. 3-4.)

Although the defendants now criticize the plaintiff's occasional reference to the 110 mg dose, the court finds that the plaintiff adhered to the court's actual ruling. Given the plaintiff's adherence, it was only fair that the defendants had to comply with the court's order as well. Yet the two articles that the defendants now claim that the court unfairly excluded would have undermined that same order. The first article is the Chan paper, which the court discussed in the preemption section and which is entitled "Is there a role for pharmacokinetic/pharmacodynamic-guided dosing for novel anticoagulants?" (Ex. 6085). The second article is one principally authored by B. Nhi Beasley of the FDA entitled "Anticoagulant Options — Why the FDA Approved a Higher but Not a Lower Dose of Dabigatran." (Ex. 5366.) These articles are obviously about dosing, the very topic that the defendants sought to exclude prior to trial. The court nonetheless did admit several sentences from the "Concluding Comments" of the Chan article, which made the defendants' ultimate point that "[r]outine PK-PD measurements ... cannot currently be recommended because of the lack of reliable tests, lack of clinical evidence of

benefit, and lack of data to guide appropriate dosing." (Ex., 6085, p. 8.)[49]

To be sure, this area was a very difficult one for the court to police. The court constantly had to exercise discretion to allow the parties to make their case while at the same time excluding many frequent references to dosing in the medical articles. The court occasionally could redact inadmissible portions of articles, but it could not rewrite or recaption the articles that the defendants offered. Had the defendants sought more carefully to use the articles in question, they might not have moved prior to trial to exclude "*any* evidence, testimony, or argument regarding the 110 mg dose of Pradaxa ...." (Emphasis added.) But having made their motion, the defendants had to live by its terms. The court finds no error in its rulings on this issue.

B. THE DEFENDANTS' CLAIM THAT PLAINTIFF'S COUNSEL'S IMPROPER BEHAVIOR UNDULY PREJUDICED THEM

The court has carefully reviewed the defendants' various claims that plaintiff's counsel engaged in improper questioning. The court finds no error in its rulings and that any error did not affect the result of the trial. In several instances, the court sustained the defendants' objections to plaintiff's questions, but the defendants still complain. The court, in any event, charged the jury that "a question is not evidence: it is the answer, not the question or the assumption made in the question, that is evidence." In some of these instances, the defendants were free to ask for limiting instructions but failed or chose not to do so.

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[49]The defendants also complain about the exclusion of slides presented by an FDA scientist as part of the FDA's pre-approval Advisory Committee meeting regarding Pradaxa. These slides identified the key points to be addressed as: "Assess the need for studying dabigatran at higher doses based on exposure-response" and "Assess the need for 110 mg dose for elderly patients." (Ex. 5785, p.3.) These key references to dosing make it virtually obvious that the slides ran afoul of the court's in limine ruling that the defendants themselves sought. In any event, the court did admit the advisory committee transcript (Ex. 5793), which would tend to make any erroneous exclusion of the slides harmless.

The trial lasted several weeks. The evidence was complex. There were four experts, numerous other doctors and scientists who testified essentially as fact witnesses, and hundreds of exhibits. There was strong and highly professional advocacy on both sides. If counsel asked an improper question or made an improper reference, opposing counsel always had the opportunity to object and ask for a limiting instruction. But nothing in the isolated incidents identified by the defendants over the course of this long trial warrants the ultimate remedy of setting the verdict aside.

C. THE DEFENDANTS' CLAIM THAT THE PLAINTIFF UNFAIRLY USED FOREIGN LABELING

The defendants assert that the plaintiff unfairly relied on Pradaxa's European label to suggest that the U.S. label should have the same content. In its ruling on the defendants' motion in limine on this issue (Entry # 283.00, p. 6.), the court adopted the ruling it had made in an earlier Pradaxa case, which provided as follows: "The plaintiff agrees that he will not attempt to show that Pradaxa does not meet foreign regulatory standards. The plaintiff may, however, introduce BI documents such as the CCDS, statements of BI, or other evidence from BI, even if made or submitted in foreign countries, to show BI's knowledge about the 150 milligram (mg.) dose of Pradaxa. The plaintiff may also introduce evidence of a foreign label if the plaintiff establishes that the label shows what BI knew or should have known about the 150 mg. dose. The defendants are entitled to a limiting instruction that such evidence is offered only to show BI's knowledge about Pradaxa and that foreign regulatory or labeling standards are irrelevant. Thus, the plaintiff may not make any arguments to the effect that, because BI told foreign doctors something about Pradaxa, it should have done so in the United States." (*Bedsole v. Boehringer Ingelheim*, HHD CV16-6070289S, Entry # 166.86.)

The court's ruling that the European Pradaxa label was admissible for the limited purpose of showing the defendants' knowledge was a correct ruling. See, e.g., *Z.H. v. Abbott Laboratories, Inc.*, No. 1:14CV176, 2017 WL 57217, at *3 (N.D. Ohio Jan. 5, 2017) ("Under Ohio law, the adequacy of Defendants' label is determined by the risks Abbott knew or should have known. Evidence of foreign labeling, prior to Z.H.'s conception, is relevant to Abbott's knowledge of the risks of Depakote.") The defendants could have requested a limiting instruction concerning foreign labels but failed to do so.

The defendants also claim that the plaintiff argued misleadingly that, based on language in the European label, "Pradaxa was inappropriate for patients with GERD in the U.S., where the 150 dose is the only dose available for the majority of patients." (Def. Motion #311.00, p. 31.) It is not possible to evaluate this claim because the defendants do not quote or cite the plaintiff's actual argument. In any event, the defendants' European label tends to show the defendants' awareness that "gastroesophageal reflux [or GERD]" is one of the "factors which may increase the haemorrhagic risk ...." (Ex. 80, p. 64.) Therefore, any argument by the plaintiff to that effect would have been entirely proper.

The only specific instance cited by the defendants occurred when the plaintiff's expert began to blurt out that this added bleeding risk may justify "a dose lower than the 150 milligrams twice a day ...." At that point, plaintiff's counsel attempted to steer the expert away from that area, the court sustained the defendants' objection, and the court sua sponte provided a limiting instruction. (5/6/19 a.m. Tr., p. 46.) Thus, it does not appear that the plaintiff's counsel made any improper use of the European label.

The court has considered the defendants' remaining claims and finds no error that would

justify setting aside the verdict and granting a new trial.

IV. DEFENDANTS' MOTION FOR COLLATERAL SOURCE REDUCTION

Pursuant to General Statutes § 52-225a, the defendants have moved for a reduction of the economic damages that the jury awarded by the amount of collateral source benefits that the plaintiff received. The court held a hearing on this issue on August 12, 2019. The relevant facts are undisputed. The jury awarded $42,464.45 in economic damages, all of which represented medical expenses for which the plaintiff was billed. The plaintiff's Medicare coverage paid $7,911.39 of these bills and the plaintiff paid $10.67. The remaining amount, $34,542.39, was adjusted or essentially written off by health care providers in favor of Medicare or Nova Health Care, which is an administrator for Medicare. (Def. Ex. 1, 8/12/19 hearing.)

The pertinent parts of § 52-225a (a) and (b) collectively provide as follows: "[i]n any civil action ... wherein liability is admitted or is determined by the trier of fact and damages are awarded to compensate the claimant, the court shall reduce the amount of such award which represents economic damages ... by an amount equal to ... [the "total amount of collateral sources which have been paid for the benefit of the claimant" minus the amount paid for those benefits] ... except that there shall be no reduction for ... a collateral source for which a right of subrogation exists ...."[50] Here, there is no dispute that Medicare paid $7,911.39 and that Medicare has a right

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[50]The full subsection (a) and the pertinent part of subsection (b) provide as follows: "(a) In any civil action, whether in tort or in contract, wherein the claimant seeks to recover damages resulting from (1) personal injury or wrongful death occurring on or after October 1, 1987, or (2) personal injury or wrongful death, arising out of the rendition of professional services by a health care provider, occurring on or after October 1, 1985, and prior to October 1, 1986, if the action was filed on or after October 1, 1987, and wherein liability is admitted or is determined by the trier of fact and damages are awarded to compensate the claimant, the court shall reduce the amount of such award which represents economic damages, as defined in subdivision (1) of subsection (a) of section 52-572h, by an amount equal to the total of amounts

of subrogation. Thus, the defendants do not seek a collateral source reduction for that amount. The defendants also do not seek a reduction for the $10.67 by the plaintiff, since he is not a collateral source. The dispute instead focuses on the $34,542.39 that the providers wrote off. The defendants claim that this amount represents a "collateral [source] which [has] been paid for the benefit of the claimant" under § 52-225a (b).

Prior to 2016, there were Superior Court decisions holding that adjustments such as those in question here were in fact collateral sources because they resembled payments for or forgiveness of a debt. See, e.g., *Bonsanti v. Newman,* No. CV030401098, 2006 WL 413011 (Conn. Super. Ct. Feb. 3, 2006). In 2016, the Connecticut Supreme Court decided *Marciano v. Jimenez*, 324 Conn. 70, 151 A.3d 1280 (2016). In that case, the Court held that, when a right of subrogation exists for a given insurance plan, there can be no collateral source reduction after trial even if there is a pretrial agreement (which was never implemented in view of the trial) to adjust the expenses to an amount less than the damages actually awarded at trial and to extinguish the plan's right of subrogation. The Court relied on what it considered the unqualified language of § 52-225a (a) providing that "there shall be no reduction for ... a collateral source for which a right of subrogation exists." The Court concluded that "when any right of subrogation exists, whether in full or in part, for a collateral source, § 52–225a precludes the trial court from ordering any

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determined to have been paid under subsection (b) of this section less the total of amounts determined to have been paid, contributed or forfeited under subsection (c) of this section, except that there shall be no reduction for (A) a collateral source for which a right of subrogation exists, and (B) the amount of collateral sources equal to the reduction in the claimant's economic damages attributable to the claimant's percentage of negligence pursuant to section 52-572h. (b) Upon a finding of liability and an awarding of damages by the trier of fact and before the court enters judgment, the court shall receive evidence from the claimant and other appropriate persons concerning the total amount of collateral sources which have been paid for the benefit of the claimant as of the date the court enters judgment."

collateral source reduction at all." Id., 77.

The defendants contend that *Marciano* does not negate the effect of the earlier decisions holding that an actual adjustment – rather than just a proposed one as in *Marciano* – constitutes a collateral source. One court has rejected this contention, stating that "the language of *Marciano* is clear in that a trial court is not permitted to grant a collateral source reduction when *any* right of subrogation exists." (Emphasis in original.) *Sutera v. Nathiello*, No. CV146022399, 2017 WL 6417801, at *2 (Conn. Super. Ct. Nov. 20, 2017).

The court agrees with this later decision. In the present case, the defendants essentially argue that Medicare and its administrators have only a partial right of subrogation based on the amounts that they actually paid. However, the *Marciano* court held that § 52–225a precludes the trial court from ordering any collateral source reduction "at all" when "any" right of subrogation exists "whether in full or in part ...." *Marciano v. Jimenez*, supra, 324 Conn. 77. The court cannot ignore this strong language. Although the defendants also present policy arguments intended to show that the plaintiff will receive a windfall in this situation, the *Marciano* Court essentially rejected these arguments by stating that "[i]f there must be a windfall certainly it is more just that the injured person shall profit therefrom, rather than the wrongdoer shall be relieved of his full responsibility for his wrongdoing.'' (Internal quotation marks omitted.) Id., 78.[51]

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[51]The defendants also rely on the post-*Marciano* ruling in *Kelly v. Annunziata*, No. HHDCV176076135S, 2019 WL 2303928 (Conn. Super. Ct. Apr. 16, 2019). But in that case there were two distinct collateral source providers, one of which had a right of subrogation and one of which did not. The court sensibly held that the exception to collateral source reduction for sources that have a right of subrogation did not apply to the insurer that had no right of subrogation. In the present case, there is essentially only one collateral source and that source has a right of subrogation.

Accordingly, under *Marciano*, the court must deny the defendants' motion for collateral source reduction.

V. CONCLUSION

The court denies the defendants' motion for judgment notwithstanding the verdict or to set aside the verdict and order a new trial. The court grants the plaintiff's motion for additur and awards punitive damages of $1. The court denies the defendants' motion for collateral source reduction. Accordingly, the court enters judgment for the plaintiff in the amount of $542,465.45.

It is so ordered.

Schuman, J.

Carl J. Schuman
Judge, Superior Court