UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

LI LIU AND DR. EMILY LIU, AS CO-ADMINISTRATORS OF THE ESTATE OF DR. ZHENSHENG LIU AND PERSONAL REPRESENTATIVE OF THE HEIRS AT LAW OF DR. LIU, Plaintiffs, v. BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM CORPORATION, BOEHRINGER INGELHEIM USA CORPORATION, AND BOEHRINGER INGELHEIM INTERNATIONAL GMBH, Defendants.	CIVIL ACTION NO. 14-13234-WGY

YOUNG, D.J. January 23, 2017

MEMORANDUM OF DECISION

I. INTRODUCTION

This diversity action arises out of the alleged wrongful death of Dr. Zhensheng Liu, due to side effects from taking the prescription drug Pradaxa. Li Liu and Dr. Emily Liu (collectively, the "Lius"), in their capacities as administrators of the estate of Dr. Zhensheng Liu and personal representatives of the heirs-at-law of that estate, have brought claims against the drug's manufacturers and distributors --

Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim Corporation, Boehringer Ingelheim USA Corporation, and Boehringer Ingelheim International GMBH (collectively, the "Defendants") -- for negligent failure to warn, negligent design defect, and negligent design and testing. The Defendants have moved for summary judgment, arguing that (1) the Lius' design claims are preempted, (2) the Lius fail to establish proximate cause, and (3) Pradaxa's label was adequate.

A. Procedural History

The Lius initially filed their complaint in this Court on August 5, 2014. Compl. & Demand Jury Trial ("Compl."), ECF No. 1. On August 18, 2014, the United States Judicial Panel on Multi-District Litigation transferred this case to the Southern District of Illinois for consolidated proceedings before Judge David R. Herndon. Joint Local Rule 16.1 Scheduling Conference Statement 2, ECF No. 27. Judge Herndon remanded the case to this Court on September 11, 2015. Id.[1] The Defendants then

[1] Discovery and other multi-district proceedings took about a year. Some of the transferred cases settled. This one did not. Judge Herndon commendably promptly sent it back to the District of Massachusetts for trial. Cf. DeLaventura v. Columbia Acorn Trust, 417 F. Supp. 2d 147 (D. Mass. 2006) (inveighing against the practice of holding cases in the transferee court to induce them to settle). Unfortunately, all parties agreed this case was not ready for trial. Another year elapsed while the parties prepared this particular case for trial. While multi-district practice has obvious consolidated cost savings for a defendant, one wonders whether doubling or trebling the time from complaint

filed the instant motion for summary judgment. Defs.' Mot. Summ. J. Basis Adequacy, Proximate Cause, & Preemption, ECF No. 41. The parties fully briefed the issues, Pls.' Mem. Law Opp'n Defs.' Mot. Summ. J. ("Pls.' Opp'n"), ECF No. 46; Mem. Law Supp. Defs.' Mot. Summ. J. Basis Adequacy, Proximate Cause, & Preemption ("Defs.' Mem."), ECF No. 42; Reply Supp. Defs.' Mot. Summ. J. Basis Adequacy, Proximate Cause, & Preemption (Defs.' Reply"), ECF No. 50, and appeared before the Court for oral argument on October 13, 2016, Electronic Clerk's Notes, ECF No. 67. After taking the matter under advisement, id., the Court partially granted the Defendants' motion for summary judgment, Order, ECF No. 71, and here explains its reasons for doing so.

B. Factual Background

Pradaxa is a brand name anticoagulation medication that was approved by the Food and Drug Administration ("FDA") in 2010. Compl. ¶ 15; Def. Boehringer Ingelheim Pharmaceuticals Inc.'s Answer Pls.' Compl. ("BIP Answer") ¶ 15, ECF No. 17; Boehringer Ingelheim Corporation's Answer Pls.' Compl. ("BIC Answer") ¶ 15, ECF No. 18; Def. Boehringer Ingelheim USA Corporation's Answer Pls.' Compl. ("BIC USA Answer") ¶ 15, ECF No. 19. It "is indicated to reduce the risk of stroke and systemic embolism in

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to trial (with the attendant costs) confers equivalent benefits on the Lius.

patients with non-valvular atrial fibrillation." Compl. ¶ 14; BIP Answer ¶ 14; BIC Answer ¶ 14; BIC USA Answer ¶ 14. Pradaxa is labeled, designed, produced, marketed, distributed, and sold by the Defendants and their agents. Compl. ¶ 13; BIP Answer ¶ 13.

Dr. Zhensheng Liu was over 80 years old and had been diagnosed with atrial fibrillation at all times relevant to this suit. See Compl. ¶ 41; Pls.' Opp'n 3; Defs.' Mem. 8. Around March 31, 2011, Dr. Seth Bilazarian ("Dr. Bilazarian") prescribed Pradaxa to Dr. Zhensheng Liu, who began using the drug. Compl. ¶ 42; Pls.' Opp'n 3; Defs.' Mem. 10. Approximately a year and a half later, on November 25, 2012, Dr. Zhensheng Liu fell and sustained a head injury. Compl. ¶ 42; Defs.' Mem. 10. He was subsequently admitted to Massachusetts General Hospital, Compl. ¶ 42; Defs.' Mem. 10, where the Lius allege that he experienced continued bleeding, prompting failed attempts to remove Pradaxa from his system through fresh frozen plasma and hemodialysis, Compl. ¶ 43. Dr. Zhensheng Liu died from cranial bleeding on November 29, 2012. Id.; Defs.' Mem. 10.

The Lius allege that neither Dr. Zhensheng Liu nor Dr. Bilazarian knew of the risks or dangers associated with Pradaxa and that, had either known, Dr. Zhensheng Liu would not have used the drug. Compl. ¶ 46. The Lius further allege that the

Defendants knew or should have known of the dangers, and through their negligence, caused Dr. Zhensheng Liu's wrongful death. Compl. ¶¶ 45, 47, 50, 54, 62, 72, 78-80, 83-85.

II. ANALYSIS

A. Legal Standard

Summary judgment is appropriate when there "'is no genuine issue as to any material fact and . . . the moving party is entitled to judgment as a matter of law.'" Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986) (quoting Fed. R. Civ. P. 56(c)). An issue is genuine if it could be "'resolved in favor of either party' at trial." Iverson v. City of Boston, 452 F.3d 94, 98 (1st Cir. 2006) (quoting Garside v. Osco Drug, Inc., 895 F.2d 46, 48 (1st Cir. 1990)). A fact is material if it could affect the outcome of the suit. Anderson, 477 U.S. at 248. In ruling on a motion for summary judgment, the Court "must draw all reasonable inferences in favor of the nonmoving party," Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000), granting the motion "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial," Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). On an issue upon which a party bears the burden of proof, absent an admission of the point, summary judgment cannot enter in favor of that party on that issue even

in the absence of contrary evidence, as the fact finder could disbelieve the proffered evidence. See Reeves, 530 U.S. at 142-43.

B. Negligent or Defective Design

The Lius argue that Pradaxa was defective in design because there were safer alternative designs, the product did not comply with its specifications or performance standards, and Pradaxa was not as safe as any other drugs in the same class. Compl. ¶ 59. They further assert that the Defendants negligently tested and designed the drug. Id. ¶¶ 67-80. The Lius, however, have produced no evidence supporting these claims. Accordingly, they have failed to establish the elements of their claims, and thus the Court granted the Defendants' motion for summary judgment on the issues of defective design and negligent design and testing.[2]

[2] The Court's resolution of the design defect claims on these grounds obviates the need for a discussion of the preemption issue, and the Court expresses no opinion thereon. The Supreme Court, however, has held that some state failure-to-warn claims are not preempted by federal law, noting that "[the manufacturer] is charged with both crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." Wyeth v. Levine, 555 U.S. 555, 571 (2009). The Supreme Court emphasized that the FDA's "changes being effected" regulation, 21 C.F.R. § 314.70(c)(6)(iii), which permits manufacturers unilaterally to add or strengthen a warning to improve drug safety, is applicable to "newly acquired information," including not only new data, but also "'new analyses of previously submitted data.'" Wyeth, 555 U.S. at 569 (quoting Supplemental Applications Proposing Labeling Changes

C. Adequacy of the Warning on Pradaxa's Label

In failure to warn cases, "the plaintiff carries the initial burden of producing sufficient evidence that the defendant manufacturer failed to warn of a non-obvious risk about which the manufacturer knew or should have known." Garside v. Osco Drug, Inc., 976 F.2d 77, 81 (1st Cir. 1992) (applying Massachusetts law). "A reasonable warning not only conveys a fair indication of the nature of the dangers involved, but also warns with the degree of intensity demanded by the nature of the risk." MacDonald v. Ortho Pharmaceutical Corp., 394 Mass. 131, 141 (1985).

This Court has noted that "it is a jury question whether [a] warning . . . [is], in fact, adequate in light of the risks that the use of [the product] presents." Lowery v. AIRCO, Inc., 725 F. Supp. 82, 85 n.2 (D. Mass. 1989) (citing MacDonald, 394 Mass. at 140); see also Fiorentino v. A. E. Staley Mfg. Co., 11 Mass. App. Ct. 428, 434 (1981).[3] Indeed, in MacDonald, the Supreme Judicial Court noted that generally, "judicial intrusion into jury decision-making in negligence cases is exceedingly

for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49603, 49609 (Aug. 22, 2008)).

[3] In Cottam v. CVS Pharmacy, 436 Mass. 316 (2006), the Supreme Judicial Court grappled with the question of whether there is a need for expert testimony so that a jury can determine the duty to warn, implying that a warning's adequacy is a question for the jury. Id. at 326.

rare." 394 Mass. at 140. The Defendants, however, refer to a recent Massachusetts Appeals Court decision, Niedner v. Ortho-McNeil Pharm., Inc., 90 Mass. App. Ct. 306 (2016), evidencing just such intrusion. Notice Suppl. Authority Supp. Defs.' Mot. Summ. J. 1-2, ECF No. 56. In Niedner, the court determined that "plain, numerous[,] and comprehensive" warnings were adequate as a matter of law when the information was "in terms understandable to a lay person." 90 Mass. App. Ct. at 312.

Here, the Lius argue that Pradaxa's label did not adequately warn of the risks associated with prescribing the drug to patients over 80 years of age, such as Dr. Zhensheng Liu. Pls.' Opp'n 8. The Lius offer the affidavits of Dr. Molofsky, Aff. Walter J. Molofsky, M.D. ("Dr. Molofsky's Aff."), ECF No. 47, and Dr. Emily Liu, Aff. Emily Liu, M.D. ("Emily Liu's Aff."), ECF No. 48, to support their claim. Both Dr. Molofsky and Dr. Emily Liu assert that the Defendants knew of an increased risk of major bleeding for patients over age 80 taking Pradaxa, the Defendants did not include this risk in the product's warning label, and Dr. Zhensheng Liu would not have taken or been prescribed Pradaxa if the Defendants had included the appropriate information in the warning. Dr. Molofsky's Aff. ¶¶ 11-39; Emily Liu's Aff. ¶¶ 11-18. Unlike in Niedner, where a label describing the risk in "no less than four places" in language "understandable to an average user," was found to be

adequate as matter of law, evaluating whether Pradaxa's warning is "plain, numerous[,] and comprehensive" requires a fact finder to weigh the evidence. See Niedner, 90 Mass. App. Ct. at 311-12. Therefore, the issues of whether the Defendants' label is adequate and how the warning applies to older patients' use of Pradaxa present questions of fact. Nonetheless, the Defendants argue that this Court ought grant summary judgment on the Lius' failure to warn claims because of the learned intermediary doctrine and lack of proximate cause. The Defendants are nearly successful; however, the Lius manage to evade summary judgment on the narrow issue of whether Pradaxa's label adequately warned of the risks of taking the drug for patients over 80 years of age.

1. Learned Intermediary

In MacDonald, the Supreme Judicial Court recognized the prescribing physician as a "learned intermediary," observing that "a patient's involvement in decision making concerning use of a prescription drug necessary to treat a malady is typically minimal or nonexistent." 394 Mass. at 137 (noting that healthy and young consumers of oral contraceptives typically play an active role in the decision to use the pill and the physician's role is rather passive). The manufacturer of a prescription drug has the duty to warn the physicians who in turn, "after considering the history and needs of their patients and the

qualities of the drug, are required to inform their patients of those side effects they determine are necessary and relevant for patients to know in making an informed decision." Cottam, 436 Mass. at 321.

The Lius contend that the "learned intermediary" doctrine is not applicable here because Dr. Zhensheng Liu and Dr. Emily Liu themselves had the required skills and education to judge whether Pradaxa would be suitable for his condition. Pls.' Opp'n 15. The Lius, however, do not provide any evidence to imply their active role in the decision to use Pradaxa. On the contrary, Dr. Emily Liu admits to a lack of "experience with Pradaxa" or in treating atrial fibrillation, as well as a failure to ask Dr. Bilazarian any questions about Pradaxa or to review the drug's label. Defs.' Reply, Ex. D, Dep. Emily Liu 6:18-20, 9:14-23, 10:24-11:4, 12:21-13:3, 16:20-23, ECF No. 50-4. She further states that Dr. Zhensheng Liu "rel[ied] exclusively on his prescribing physicians to become familiar with the risks and benefits of prescription medications." Id. at 8:16-9:23. Accordingly, the Lius have failed to provide evidence that the "learned intermediary" doctrine does not apply here.

2. Proximate Cause

"'[G]enerally, questions of causation, proximate and intervening, present issues for the jury to decide.'" Garside,

976 F.2d at 81 (quoting Solimene v. B. Grauel & Co., 399 Mass. 790, 794 (1987)).

> Under Massachusetts law, therefore, the burden shifting in a failure to warn case such as the instant one works as follows: (1) the plaintiff carries the initial burden of producing sufficient evidence that the defendant manufacturer failed to warn of a non-obvious risk about which the manufacturer knew or should have known; (2) assuming the plaintiff raises a triable issue on this question, a rebuttable presumption arises that the physician would have heeded an adequate warning; (3) defendant must then come forward with sufficient evidence to rebut that presumption; and (4) once the presumption is rebutted, plaintiff must produce sufficient evidence to create a triable issue on the question of causation.

Id. (citations omitted).

The Lius argue that to prove proximate cause they need only show that, had the warnings been adequate, Dr. Bilazarian would have changed his prescribing decision. Pls.' Opp'n 13-14. The Lius further claim that it is presumed that Dr. Bilazarian would have heeded an appropriate warning. Id. at 13. Indeed, in Cottam, the Supreme Judicial Court held that "Massachusetts law permits the jury to infer that a warning, if properly given, would have been followed." 436 Mass. at 327.

Here, the initial burden is on the Lius to prove causation by showing that if the proper warning and information had been provided, Dr. Bilazarian would not have prescribed Pradaxa to a patient like Dr. Zhensheng. See Garside, 976 F.2d at 81. As discussed above, the Lius produce the affidavits of Dr. Emily

Liu and Dr. Molofsky which suggest inadequacies in the warnings by the Defendants. This raises the rebuttable presumption that, had Dr. Bilazarian been adequately warned, he would have changed his decision to prescribe Pradaxa. See Knowlton v. Deseret Med., Inc., 930 F.2d 116, 123 (1st Cir. 1991).

This presumption, in turn, shifts the burden of going forward to the Defendants. See id. They carry their burden in spades, turning to Dr. Bilazarian himself. During Dr. Bilazarian's deposition, the Lius' counsel made Dr. Bilazarian aware of a clinical study that concluded: "Dabigatran [Pradaxa's chemical name] was associated with a higher incidence of major bleeding, regardless of the anatomical site. In addition, dabigatran was associated with higher risk of gastrointestinal bleeding, but a lower risk of intracranial hemorrhage than warfarin." Defs.' Mem., Ex. 2, Dep. Seth Bilazarian, M.D. 37:14-38:9, ECF No. 42-2. The Lius' counsel then asked: "So, if at the time . . . you were aware of this clinical information, would you have still put [Dr. Zhensheng Liu] on Pradaxa?" Id. at 38:12-16. Dr. Bilazarian responded, "Yes." Id. at 38:19. Counsel then persisted: "[W]ould you not have concluded that warfarin posed a safer alternative as a blood thinner anticoagulant for Dr. [Zhensheng] Liu than the Pradaxa that he was put on by you?" Id. at 39:16-20. Dr. Bilazarian stated, "I would not have concluded that." Id. at 39:24.

Dr. Bilazarian's responses extinguish the presumption, W.G. Young, J.R. Pollets & C. Poreda, Massachusetts Evidence 2d Ed. § 301.1 (3d ed. 2016), in so far as it pertains to the risk of internal hemorrhaging -- the risk that caused Dr. Zhensheng Liu's death. Absent the presumption, there is no evidence here that the warnings were inadequate to advise a physician of the risks of internal hemorrhaging; further, Dr. Bilazarian, as a learned intermediary, breaks the chain of proximate causation as to these Defendants.

The Lius nevertheless escape summary judgment although their case dangles by a most tenuous thread, viz. that Pradaxa is especially risky for a patient of Dr. Zhensheng Liu's age, that the warning should have so indicated, and if it had, Dr. Bilazarian would not have prescribed it. Dr. Molofsky's Aff. ¶¶ 11-12, 13-15, 16. The questions put to him at his deposition do not go this far and, since all reasonable inferences must be drawn in favor of the non-movant, the plaintiffs here, Reeves, 530 U.S. at 150, this case ought proceed to trial.

III. CONCLUSION

For the foregoing reasons, this Court on October 18, 2016, GRANTED IN PART and DENIED IN PART the Defendants' motion for summary judgment, ECF No. 41. Summary judgment is GRANTED as to

the claims of negligent design and testing; it is DENIED as to the adequacy of Pradaxa's label and proximate cause.

SO ORDERED.

/s/ William G. Young
WILLIAM G. YOUNG
DISTRICT JUDGE