UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SHEILA FORTNER,	:	17cv1562 (DLC)
Plaintiff,	:	OPINION AND ORDER
-v-	:	
BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC.,	:	
Defendants.	:	

APPEARANCES:

For Sheila Fortner:
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Robert L. Salim
Salim-Beasley, LLC
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For Bristol-Myers Squibb Company and Pfizer Inc.:
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DENISE COTE, District Judge:

Plaintiff Sheila Fortner ("Fortner") brings this product liability lawsuit against defendants Bristol-Myers Squibb Company ("BMS") and Pfizer Inc. ("Pfizer"), alleging that she suffered gastrointestinal bleeding caused by taking Eliquis, a prescription drug manufactured, marketed, and distributed by the

defendants. Two previous Opinions addressed Eliquis product liability claims -- Utts v. Bristol-Myers Squibb Co. & Pfizer Inc., 16cv5668 (DLC), 2016 WL 7429449 (S.D.N.Y. Dec. 23, 2016) ("Utts I"), and Utts v. Bristol-Myers Squibb Co. & Pfizer Inc., 16cv5668 (DLC), 2017 WL 1906875 (S.D.N.Y. May 8, 2017) ("Utts II") -- and explained the principles of preemption that govern state law failure to warn and design defect claims against brand name drug manufacturers. The Utts Opinions further addressed whether the Eliquis complaints at issue satisfied the pleading standards of Rules 8(a) and 9(b), Fed. R. Civ. P. Plaintiff in this action was given an opportunity to amend her complaint in light of the analyses in Utts I and Utts II. The plaintiff's amended complaint fails to correct the pleading deficiencies described in Utts I and Utts II, and largely for the reasons set forth in the Utts Opinions, the present action is dismissed with prejudice.

PROCEDURAL HISTORY

As of June 20, 2017, this case was one of 68 actions in In re: Eliquis Products Liability Litigation, 17md2754, a Multidistrict Litigation (MDL) assigned to this Court. There are currently nineteen active cases in this litigation.[1]

[1] Twenty-four cases were voluntarily dismissed, while another twenty-four cases were dismissed with prejudice on June 26, 2017. The Utts action was dismissed with prejudice on May 8, 2017.

On November 21, 2016, parties in seventeen related Eliquis actions filed in the Southern District of New York were given the opportunity to identify one or two actions to proceed with early motion practice. On December 2, the parties agreed to proceed with a motion to dismiss in Utts v. Bristol-Myers Squibb Co. & Pfizer Inc., 16cv5668 (DLC) ("Utts"). On December 23, the Utts I Opinion dismissed the Utts complaint with leave to amend most of the plaintiffs' claims. On May 8, 2017, the Utts II Opinion dismissed the second amended complaint in Utts in its entirety and with prejudice.

Meanwhile, on February 7, the Judicial Panel on Multidistrict Litigation ("JPML") transferred In re: Eliquis Products Liability Litigation, 17md2754, to this Court. At a March 17 conference, the parties in the MDL agreed to have the Court decide the renewed motion to dismiss in Utts and, if that motion were granted, to give all other actions in the MDL one final opportunity to amend in light of the analysis that would be forthcoming in Utts.[2] On May 9, in light of Utts II, all

[2] The reasoning for adopting an OTSC procedure was explained at the March 17 conference as follows:

> [The remaining actions] will have had [the Court's] first decision in Utts, they will have had a second decision in Utts, they will have seen the way the Utts complaint evolved over time, and if they think they can improve upon it or distinguish themselves through a pleading that can survive, then [the Court] would like to give them that opportunity to do so.

None of the parties objected to this OTSC procedure.

remaining plaintiffs in actions pending before this Court as of that date were given the opportunity to file an amended complaint by May 23 and were required to show cause why their complaints should not be dismissed based on the analyses in Utts I and Utts II (the "May 9 OTSC").[3]

Plaintiffs in nineteen actions timely responded to the Court's May 9 OTSC. Thirteen, including this plaintiff, are represented by the law firm of Salim-Beasley, LLC.

BACKGROUND

Fortner is a resident of Tennessee. Fortner was prescribed Eliquis by her physician to reduce her risk of stroke and embolism. She suffered gastrointestinal bleeding after taking Eliquis.

Fortner originally filed her complaint against the defendants on August 1, 2016, in the Eastern District of Tennessee. On October 24, the Tennessee district court entered a stay pending resolution of the defendants' petition to the JPML. On March 2, 2017, the JPML transferred Fortner's lawsuit to this Court. On May 23, Fortner filed her first amended complaint ("FAC") and a memorandum in response to the May 9

[3] The May 9 OTSC also established a schedule for any later-transferred or reassigned action. All such cases would have fourteen days following arrival on the Court's docket to file an amended complaint and show cause why the amended complaint should not be dismissed in light of the Utts II Opinion.

OTSC.[4] On June 20, the defendants filed an omnibus reply to each action that responded to the May 9 OTSC.

The FAC asserts eight causes of action against the defendants. They are claims for: (1) negligence; (2) strict products liability; (3) breach of express warranty; (4) breach of implied warranties; (5) fraudulent misrepresentation; (6) fraudulent concealment; (7) negligent misrepresentation; and (8) violation of Tennessee's consumer protection laws.

DISCUSSION

The federal standards for pleading, including for pleading any claim to which Rule 9(b) of the Federal Rules of Civil Procedure applies, are set forth in Utts II, and are incorporated by reference. Utts II, 2017 WL 1906875, at *6. Under those standards, the Eliquis label is integral to the FAC. Id.

I. Preemption

The Utts Opinions set forth certain fundamental preemption principles that govern the design defect and failure to warn claims against manufacturers of branded pharmaceuticals, irrespective of state product liability law. First, pre-FDA approval design defect and failure to

[4] On May 30, Fortner filed a notice of errata correcting a typo in her May 23 memorandum.

warn claims are preempted under federal law. See Utts I, 2016 WL 7429449, at *9, *12; Utts II, 2017 WL 1906875, at *9. Second, post-approval design defect claims are preempted under federal law where FDA regulations prohibit a change of the type implicated by the claim. See Utts I, 2016 WL 7429449, at *9; Utts II, 2017 WL 1906875, at *5. Third, post-approval failure to warn claims are preempted unless the plaintiff can plausibly allege that there existed "newly acquired information" such that, pursuant to the Changes Being Effected ("CBE") regulation, the defendants could independently have updated the Eliquis label to include such warnings. See Utts I, 2016 WL 7429449, at *11; Utts II, 2017 WL 1906875, at *9. Thus, an analysis of state law claims is unnecessary unless the plaintiff plausibly alleges the existence of newly acquired information.

The FAC alleges that Eliquis was defective because it was manufactured and distributed without an effective antidote or an Eliquis-specific test to monitor the drug's anticoagulation effect. The FAC further criticizes Eliquis' twice daily dosing regimen. Such claims are directed toward Eliquis' design and are preempted for the reasons set forth in Utts I, 2016 WL 7429449, at *9, *11-12, and Utts II, 2017 WL 1906875, at *5, *9. The FAC also

asserts that the Eliquis label did not adequately warn of irreversible bleeding events, the inability to measure the drug concentration of Eliquis, or the lack of an antidote. These are essentially design defect claims. But, even if they are understood as failure-to-warn claims, the FAC does not plausibly allege that newly acquired information existed that would have permitted the defendants to alter the Eliquis label pursuant to CBE regulations. See, e.g., Utts II, 2017 WL 1906875, at *16. These claims are therefore preempted as well.

In her May 23 memorandum, the plaintiff principally argues for reconsideration of Utts' analysis of the preemption of "pre-FDA" design defect claims. This request is denied. The plaintiff has identified no binding authority that contradicts or disagrees with the Utts design defect analysis. In fact, the only appellate court to have considered this issue held that all pre-approval design defect claims are preempted. See Yates v. Ortho-McNeil-Janssen Pharm., 808 F.3d 281, 299 (6th Cir. 2015).[5]

[5] The plaintiff contends that Utts' design defect preemption analysis does not apply because unlike California, Tennessee still recognizes strict liability design defect claims against prescription drug manufacturers. This argument misunderstands the scope of the preemption analysis in Utts I, which held that all design defect claims -- whether brought under a negligence or strict liability theory -- are preempted because brand name drug manufacturers lack the authority to alter a drug's design

To avoid the application of Utts' preemption analysis to the FAC, the plaintiff makes one other argument. She points out that neither her original complaint nor the FAC "include any of the attachments discussed, quoted, examined, and analyzed by the Court in Utts."[6] This pleading tactic, however, does not avoid a preemption analysis. As explained in Utts I, if a pleading plausibly alleges the existence of newly acquired information that would permit a manufacturer to unilaterally amend a label without FDA approval, "then there may be no preemption of the state law claim." Utts I, 2016 WL 7429449, at *9. The FAC fails to allege that there was any such newly acquired information.

The FAC's references to adverse information concerning the risks associated with Eliquis are conclusory and vague. In drafting the FAC, the plaintiff has chosen to repeat some of the allegations in the Utts second amended

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at the time the New Drug Approval ("NDA") process concludes. Moreover, in her May 23 memorandum, the plaintiff cites California law -- not Tennessee law -- to support her claim that Tennessee recognizes strict liability design defect claims.

[6] The primary difference between the plaintiff's original complaint and the FAC appears to be the inclusion in the "Factual Background" section of references to studies and analyses of Eliquis' adverse effects, as well as some information concerning Eliquis' advertising and marketing campaigns.

complaint, but in less detail and without identifying or appending the specific studies from which these allegations are drawn. The actual findings from these various studies were evaluated at length in Utts II. For example, the FAC references adverse event report data from 2014. Utts II analyzed this adverse event data when it evaluated whether the data described in The Institute for Safe Medical Practices QuarterWatch Report (the "ISMP Report") constituted newly acquired information. See Utts II, 2017 WL 1906875, at *11-14. To give another example, the FAC alleges that "meta-analysis shows that the NOACs, including Eliquis, are no more effective than warfarin in preventing ischemic strokes." Utts II addressed this finding in its discussion of the ISMP Report and the British Medical Journal Study (the "BMJ Study"). See id. at *14-15.

The plaintiff cannot escape Utts II's preemption analysis by masking the basis for her claim. The FAC does not plausibly allege that any newly acquired information exists, as that term is defined under the law, and its claims do not become more plausible simply because the plaintiff has omitted from the FAC the sources upon which her conclusory factual allegations are based. As written, the FAC simply does not provide sufficient factual content to support a plausible inference that there exists newly

acquired information such that the defendants could unilaterally have changed the Eliquis label to include additional warnings. Accordingly, the plaintiff's failure to warn claims, as well as each of her design claims, are preempted and dismissed with prejudice.

II. Adequacy of the Eliquis Label

There is a second, independent reason for dismissing the FAC's claims concerning the Eliquis label's warnings. Under Tennessee law,[7] warnings concerning prescription drugs generally are adequate when they contain "a full and complete disclosure of the potential adverse reactions to the drug." Strayhorn v. Wyeth Pharm., Inc., 737 F.3d 378, 393 (6th Cir. 2013) (citation omitted). "A reasonable warning not only conveys a fair indication of the dangers involved, but also warns with the degree of intensity required by the nature of the risk." Id. (citation omitted). Among the criteria for determining the adequacy of a warning are:

> 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it and, 5. the means to convey the

[7] It is undisputed that Tennessee law controls the FAC's claims.

warning must be adequate.

Pittman v. Upjohn Co., 890 S.W.2d 425, 429 (Tenn. 1994) (citation omitted). "The adequacy of a drug manufacturer's warnings is normally a question of fact," but can become a question of law "when the instructions are accurate and unambiguous." Id. (citation omitted).

Tennessee follows the learned intermediary doctrine, which is "applicable in failure to warn suits where a physician is the intermediary between a defendant pharmaceutical or other medical product manufacturer and an injured patient." Nye v. Bayer Cropscience, Inc., 347 S.W.3d 686, 701 (Tenn. 2011). Thus, "a pharmaceutical manufacturer can discharge its duty to warn by providing the physician with adequate warnings of the drug's risks." Id.

Tennessee law does not materially differ from California law, insofar as both states have adopted the learned intermediary doctrine and require a drug manufacturer to warn in unambiguous terms of the specific risk that caused injury to the plaintiff. See Utts II, 2017 WL 1906875, at *20 ("A written warning is adequate if it directly warns in plain and explicit terms of the specific risk that has caused injury to the plaintiff." (citing Kearl v. Lederle Labs., 218 Cal. Rptr. 453, 467

(Ct. App. 1985)). Thus, the analysis performed in Utts II to assess the adequacy of the Eliquis label is equally applicable here.

The FAC alleges that the Eliquis labeling inadequately warns about such things as the risk of bleeding, the need for monitoring, and dosage recommendations. It identifies no risks that were not identified in the Utts' complaint and no risks that were not analyzed in Utts II. For the reasons explained in Utts II, the Eliquis label adequately warns about each of these risks. See Utts II, 2017 WL 1906875, at *20-22. The plaintiff's May 23 memorandum does not suggest otherwise. Thus, for the reasons set forth in Utts II, the Eliquis label is adequate as a matter of law.

III. The FAC's Causes of Action

To clarify the extent to which the FAC's claims can be resolved on grounds of preemption or adequacy, each cause of action is addressed separately below.

A. Negligence and Strict Liability

The FAC alleges that the plaintiffs should be held liable under theories of negligence and strict liability for the above-mentioned design defects and labeling inadequacies. All of the plaintiff's design defect claims are preempted. Insofar as the plaintiff's negligence and strict liability causes of action are based on the

defendants' failure to warn of known or knowable risks, such claims are dismissed with prejudice because, as described above, the plaintiff has not plausibly alleged the existence of newly acquired information and the Eliquis label is also adequate as a matter of law.

B. Breach of Express and Implied Warranties

The FAC fails to identify particular statements upon which its warranty claims are based or how such warranties were breached. These were flaws identified both in Utts I and Utts II. See Utts I, 2016 WL 7429449, at *13; Utts II, 2017 WL 1906875, at *24. Thus, for the reasons explained in Utts I and Utts II, the warranty claims are dismissed with prejudice.

C. Fraud Causes of Action

The FAC's fraudulent concealment and negligent misrepresentation claims repeat, word for word, those dismissed in Utts I. And while the Utts I complaint did not have a "fraudulent misrepresentation" claim, its "fraud" claim does not differ substantially in substance or nature from the FAC's "fraudulent misrepresentation" claim. Thus, for the reasons set forth in Utts I -- specifically, preemption under Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), and failure to meet Rule 9(b)'s heightened pleading standards -- the plaintiff's

fraud causes of action are dismissed with prejudice. Utts I, 2016 WL 7429449, at *14-15.[8]

D. Tennessee Consumer Protection Laws

The FAC alleges a violation of Tennessee's Consumer Protection Act ("TCPA"). The TCPA is a statute "designed to protect Tennessee consumers from unfair and deceptive practices in the course of trade and commerce." Pagliara v. Johnston Barton Proctor & Rose, LLP, 708 F.3d 813, 819 (6th Cir. 2013). In order to state a claim under the TCPA, a plaintiff must show: "(1) that the defendant engaged in an unfair or deceptive act or practice and (2) that the plaintiff suffered an ascertainable loss of money or property as a result." Id. (citation omitted). The TCPA applies only to "acts affecting the conduct of any trade or commerce, including acts that are a part of the advertising, offering for sale, lease or rental, or distribution of any goods, services or property." Id. (citation omitted).

The FAC alleges that the defendants acted unfairly and deceptively in: (1) publishing instructions and product material containing inaccurate and incomplete factual information; (2) misrepresenting the nature, quality, and characteristics of

[8] Insofar as the plaintiff's May 23 memorandum contends that her fraud claims are adequately pled under Tennessee pleading standards, this argument is flawed. The Federal Rules of Civil Procedure govern the adequacy of pleadings in federal court, not state law.

Eliquis; and (3) engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding. In particular, the plaintiff claims that the defendants misrepresented the alleged benefits of Eliquis and failed to disclose material information concerning known side effects.

For the reasons set forth in Utts II, the FAC's consumer protection claims are preempted and fail as well to meet the pleading standards under Rules 8(a) and 9(b), Fed. R. Civ. P. The FAC does not specify the contents of the fraudulent misrepresentations, when such misrepresentations were made, and why such representations were, at the very least, misleading to a reasonable consumer. Nor does the FAC plausibly allege that there exists certain information or data that somehow undermined or contradicted the information communicated through Eliquis' labeling and advertising. Accordingly, Fortner's consumer protection claims are dismissed for failing to plausibly allege that the defendants' advertising contained false or even misleading representations. See Utts II, 2017 WL 1906875, at *29.

VII. Request for Remand

In her response memorandum, Fortner suggests that this case be remanded to the Eastern District of Tennessee. Under 28 U.S.C. § 1407(a):

> When civil actions involving one or more common question of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made by the judicial panel on multidistrict litigation . . . for the convenience of parties and witnesses and [to] promote the just and efficient conduct of such actions. Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated.

(Emphasis added.) Pursuant to Rule 10.1(b), Rules of Procedure of the Judicial Panel on Multidistrict Litigation, the Panel shall consider the question of remand on the suggestion of the transferee court, on the Panel's own initiative, or by motion of any party.

While a transferee court may not assign to itself for trial a case transferred for pre-trial purposes, Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach, 523 U.S. 26 (1998), it has long been the province of the transferee court to enter dispositive pre-trial orders terminating cases. See, e.g., In re Donald J. Trump Casino Secs. Litig.-Taj Mahal Litig., 7 F.3d 357, 367 (3d Cir. 1993) ("[T]ransferee courts frequently terminate consolidated cases in practice."), Stanley A. Weigel, The Judicial Panel on Multidistrict Litigation, Transferor Courts and Transferee Courts, 78 F.R.D. 575, 582 (1978) ("It is generally accepted that a transferee judge has authority to decide all pretrial motions, including motions that may be

dispositive, such as motions . . . for dismissal . . . ."). The request for a remand is denied.

CONCLUSION

The amended complaint is dismissed with prejudice. The Clerk of Court shall enter judgment for the defendants and close this case.

Dated: New York, New York
July 26, 2017

DENISE COTE
United States District Judge