IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

SUSAN SCHROCK and STEVE SCHROCK,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. CIV-08-453-M
	)	
WYETH, INC., et al.,	)	
	)	
Defendants.	)	

ORDER

Before the Court is "Defendants' Motion to Dismiss Based on Federal Preemption" [docket no. 75], filed on August 27, 2008. On September 15, 2008, plaintiffs filed their response, and on September 26, 2008, defendants Pliva USA, Inc. ("Pliva") and Barr Pharmaceuticals, Inc. ("Barr") filed their reply. Also before the Court is the "Motion to Dismiss of Defendant Actavis, Inc. and Actavis-Elizabeth, L.L.C." [docket no. 71], filed August 26, 2008. On September 15, 2008, plaintiffs filed their response, and on September 25, 2008, defendants Actavis, Inc. ("Actavis") and Actavis-Elizabeth, L.L.C. ("Actavis-Elizabeth") filed their reply. Furthermore, defendants Wyeth and Schwarz Pharma, Inc. ("Schwarz") bring a Motion for Summary Judgment [docket no. 92], filed October 29, 2008. On November 17, 2008, plaintiffs filed their response, and on December 15, 2008, defendants Wyeth and Schwarz filed their reply. Based upon the parties' submissions, the Court makes its determination.

I. Background

In their Complaint, plaintiffs allege that in March of 2000, Susan Schrock's physician prescribed the drug Reglan to her to treat reflux, a gastroesophageal condition. The active ingredient in Reglan is metoclopramide ("MCP"). MCP, which is available in brand (Reglan) or generic form, is used to treat certain gastrointestinal disorders. Mrs. Schrock alleges that she ingested the generic

form of Reglan from March 2000 until June 2006, and that her long-term ingestion of the prescription drug caused her to develop tardive dyskinesia, a neurological movement disorder.

Plaintiffs assert state-law tort claims against defendants Wyeth and Schwarz as the manufacturers and distributors of the brand name Reglan, and against the remaining defendants as manufacturers and distributors of the generic MCP. At the core of all of plaintiffs' claims is the basic assertion that defendants failed to adequately warn about the association between long-term ingestion of MCP and movement disorders. For example, plaintiffs allege that some or all defendants ignored scientific and medical literature establishing a higher risk of developing tardive dyskinesia, failed to request a labeling change revision to the United States Food and Drug Administration ("FDA"), and failed to report safety information directly to the medical community.

Defendants Pliva and Barr and Actavis and Actavis-Elizabeth separately move to dismiss plaintiffs' claims against them, arguing that plaintiffs' claims are preempted by federal law. Defendants Wyeth and Schwarz move for summary judgment on the basis that as brand name manufacturers and distributors they cannot be liable for harm caused by the generic manufacturers of the prescription drug.

II. Motions to Dismiss

1. Standard for Dismissal

"[A] complaint should not be dismissed for failure to state a claim unless it appears...plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Bell Atl. Corp. v. Twombly*, 127 S. Ct. 1955, 1968 (2007). The relevant inquiry is whether the complaint contains enough facts to state a claim to relief that is plausible on its face. *Ridge at Red Hawk, L.L.C. v. Schneider*, 493 F.3d 1174, 1177 (10th Cir. 2007). The issue in reviewing the sufficiency of plaintiffs'

complaint is not whether they will prevail, but whether they are entitled to offer evidence to support their claims. *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974). The Court must assume as true all well pleaded facts in plaintiffs' complaint and view them in a light most favorable to plaintiffs. *Zinermon v. Burch*, 494 U.S. 113, 118 (1990); *Sutton v. Utah State Sch. For the Deaf and Blind*, 173 F.3d 1226, 1236 (10th Cir. 1999). However, the Court need not accept as true plaintiffs' conclusory allegations. *Hall v. Bellmon*, 935 F.2d 1106, 1110 (10th Cir. 1991).

2. Discussion

Defendants Pliva, Barr, Actavis and Actavis-Elizabeth assert a number of arguments in support of their position that the claims asserted in the instant action are preempted by federal law. The United States Supreme Court, however, has recently spoken on the issue of whether the FDA's approvals provide a defendant with a complete defense to state law tort claims based upon the failure to warn and concluded they do not.

In *Wyeth v. Levine*, No. 06-1249, --- S. Ct. ----, 2009 WL 529172 (U.S. Mar. 4, 2009), "Wyeth [made] two separate preemption arguments: first, that it would have been impossible for it to comply with the state-law duty to modify [the prescription drug's] labeling without violating state law, and second, that recognition of [the] state tort action creates an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress because it substitutes a lay jury's decision about drug labeling for the expert judgment of the FDA." *Id*. at *5 (citations and quotations omitted). In the instant case, defendants collectively assert similar, if not the identical, arguments in support of federal preemption of plaintiffs' state law claims.

In resolving these arguments, the *Wyeth* Court relied on two cornerstones of preemption jurisprudence: first, "the purpose of Congress is the ultimate touchstone in every preemption case"

and second, that courts must start with the "assumption that historic police powers of the state are not to be superceded by the Federal Act unless that was clear and manifest purpose of the Congress." *Id*. With respect to a change in drug labels based upon safety information which becomes available after a drug's initial approval, Congress "adopted a rule of construction to make it clear that manufacturers remain responsible for updating their labels." *Id*. Furthermore, "a central premise of federal drug regulation [is] that the manufacturer bears responsibility for the content of its label at all times," and "is charged with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at *8. Unless the prescription drug manufacturer makes a clear evidentiary showing that the FDA would not have approved a change to the label, a court may not conclude that it was impossible for the prescription drug manufacturer to comply with both federal and state requirements. *Id.* at *9. Accordingly, a court cannot accept a prescription drug manufacturer's contention that the FDA would have prevented it from adding a stronger warning. *Id*. As the *Wyeth* Court observed, "[i]mpossibility pre-emption is a demanding defense." When the regulation permits a prescription drug manufacturer to unilaterally strengthen its warning, the mere fact that the FDA approved a prescription drug label does not establish that it would have prohibited such a change. *Id*. In this case, the Court finds that it is not impossible to comply with both federal and state requirements.

The petitioner in the *Wyeth* case also argued that requiring it to comply with a state-law duty to provide stronger warnings would obstruct the purposes and objectives of federal drug labeling regulation. *Id.* at *10. In support of its argument, the petitioner in the *Wyeth* case contended that the applicable statute establishes both a floor and ceiling for drug regulation in that once the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate, regardless of

whether there is any evidence that the FDA has considered the stronger warning at issue. *Id*. However, the *Wyeth* Court held "[i]f Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the [relevant statute's] 70-year history." *Id*. Because Congress has not exacted such a provision for prescription drugs although it was aware of the prevalence of state tort litigation, the *Wyeth* Court pronounced this as powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. *Id.* Furthermore, a court may not rely on the FDA's proclamation of preemption absent the substance of state or federal law. *Id.* at *11.

Defendants in this case have proffered similar, if not identical, arguments concerning the obstruction of the purposes and objectives of federal drug labeling regulation. As in *Wyeth*, however, this Court finds that there is a longstanding coexistence of state and federal law in the regulatory history and background relevant to this case. Therefore, the Court finds that this state-law action does not obstruct the purposes and objectives of Congress. In fact, "[f]ailure-to-warn actions, in particular, lend force to the [relevant statute's] premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Id*. at *12.

As to any remaining basis which defendants have presented in the instant matter, the United States Supreme Court has clearly concluded that Congress did not intend the preempt state-law failure-to-warn actions.

Accordingly, the Court denies the motions to dismiss as to the preemption by federal laws.

III. Motion for Summary Judgment

1. Standard for Summary Judgment

"Summary judgment is appropriate if the record shows that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. The moving party is entitled to summary judgment where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party. When applying this standard, [the Court] examines the record and reasonable inferences drawn therefrom in the light most favorable to the non-moving party." *19 Solid Waste Dep't Mechanics v. City of Albuquerque*, 156 F.3d 1068, 1071-72 (10th Cir. 1998) (internal citations and quotations omitted).

"Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Furthermore, the non-movant has a burden of doing more than simply showing there is some metaphysical doubt as to the material facts. Rather, the relevant inquiry is whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Neustrom v. Union Pacific R.R. Co.*, 156 F.3d 1057, 1066 (10th Cir. 1998) (internal citations and quotations omitted).

2. Discussion

In their motion for summary judgment, defendants Wyeth and Schwartz assert that Oklahoma law has never imposed a duty upon a brand name drug manufacturer to warn about the risks associated with the use of a generic drug manufactured and sold by another company. Further, the parties do not dispute that Mrs. Schrock did not use the brand name prescription drug manufactured by either of these defendants. Therefore, defendants Wyeth and Schwarz contend plaintiffs cannot establish essential elements of their claims because defendants Wyeth and Schwartz owed no duty

to plaintiffs.

In response, plaintiffs assert that Oklahoma law is consistent with a drug originator's liability for its warning through bioequivalent drugs. However, as stated "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Wyeth*, 2009 WL 529172 at *8. Indeed, regardless of the theory of recovery advanced, the "responsibility for the defect must still be traced to the proper defendant."

Plaintiffs also argue that defendants Wyeth and Schwarz as brand manufacturers of the generic drug in question had a heightened duty under the FDA regulations to exercise reasonable care to ensure the prescription drug label is accurate and not misleading. Plaintiffs, however, offer no binding authority for this extraordinary contention. Recognition of such a duty would constitute new Oklahoma law, and as the Tenth Circuit instructed: "As a federal court, we are generally reticent to expand state law without clear guidance from its highest court." *Taylor v. Phelan*, 9 F.3d 882, 887 (10th Cir. 1993).

Finally, plaintiffs opine that they would be denied of any remedy if the generic manufacturers are not responsible due to federal preemption, and the brand name manufacturers are similarly not responsible. The Court finds, however, that this is no longer an issue in light of the earlier finding that plaintiffs are not preempted by federal law from pursuing their state law claims.

Having reviewed the parties' submissions, the Court also finds that the imposition of liability on brand name manufacturers for injuries caused by competitor generic manufacturers is inconsistent with Oklahoma law, precedents from other jurisdictions and sound public policy. Specifically, Oklahoma has rejected market share liability, alternative liability theory, the concert

of action theory and enterprise liability. *Case v. Fibreboard Corp.*, 743 P.2d 1062, 1067 (Okla. 1987). However, plaintiffs cannot show how liability extends to defendants Wyeth and Schwarz absent a causative link between the specific tortious link and plaintiffs injuries in their claims for products liability under Oklahoma law. Plaintiffs did not purchase or ingest MCP manufactured by either defendant Wyeth or Schwarz. Furthermore, there is no product identification with respect to these defendants. Therefore, there is no legal support for plaintiffs' attempt to extend liability to manufacturers who did not distribute the product to Mrs. Schrock.

Furthermore, twenty four courts in fourteen different states have rejected the assertion that defendants have a duty to warn about products they did not manufacture. Given these defendants have no relationship with plaintiffs in the instant case, the Court finds that holding defendants Wyeth and Schwarz liable under the circumstances would "extend the concept of duty beyond reason and good sense" as a matter of public policy. *Rose v. Sapulpa Rural Water Co.*, 631 P.2d 752, 757 (Okla. 1981).

Having reviewed the parties' submissions, the Court concludes that a cause of action does not lie against defendants Wyeth and Schwarz on any of the above proffered bases. Accordingly, the Court grants defendants Wyeth and Schwarz' motion for summary judgment.

IV. Conclusion

For the reasons set forth above, the Court hereby DENIES defendants Pliva, Barr, Actavis and Actavis-Elizabeth's motions to dismiss and GRANTS defendants Wyeth and Schwarz' motion for summary judgment.

IT IS SO ORDERED this 11th day of March, 2009.

VICKI MILES-LaGRANGE
CHIEF UNITED STATES DISTRICT JUDGE