IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
SOUTHERN DIVISION

DANNY WEEKS, *et al.,*	)	
	)	
Plaintiffs,	)	
v.	)	CASE NO. 1:10-cv-602-MEF
	)	
WYETH, INC., *et al.*,	)	
	)	
Defendants.	)	

O R D E R

Pursuant to Ala. R. App. P. 18, the United States District Court for the Middle District of Alabama, Southern Division, requests the Supreme Court of Alabama to answer a question of law which is deemed determinative of an action before said federal court and to which there is no clear controlling precedent in the decisions of the Supreme Court of Alabama.

In support of said certificate, the following facts are shown to the Court:

(1) ***Style of the Case***

Danny Weeks and Vicki Weeks v. Wyeth, Inc.; Pfizer, Inc.; Schwarz Pharma, Inc.; Actavis Elizabeth, LLC.; and Teva Pharmaceuticals USA.

(2) ***Statement of Facts***

Plaintiffs Danny and Vicki Weeks filed this action against five current and former drug manufacturers for injuries that Mr. Weeks allegedly suffered as a result of his long-term use of the prescription drug product metoclopramide, which is the generic form of the brand-name drug

Reglan®. The Weekses claim that two companies—Teva Pharmaceuticals USA and Actavis Elizabeth, LLC—manufactured and sold the generic metoclopramide that Mr. Weeks ingested.

The Weekses concede that Mr. Weeks did not ingest any Reglan® manufactured by the three brand-name defendants, Wyeth LLC, Pfizer Inc., and Schwarz Pharma, Inc. The Weekses nonetheless assert that the brand-name defendants are liable for Mr. Weeks's harm on fraud, misrepresentation, and/or suppression theories because they at different times manufactured or sold brand-name Reglan® and purportedly either misrepresented or failed adequately to warn Mr. Weeks and his physician about the risks of using Reglan® long-term. The brand-name defendants moved to dismiss the claims against them, arguing, among other things, (1) that the Weekses' claims, however pled, are in fact product liability claims that are barred for failure of "product identification" and (2) that they had no duty to warn about the risks associated with ingestion of their competitors' generic products. The Weekses responded to the brand-name defendants' motion, and the defendants replied. On March 31, 2011, this Court granted in part and denied in part the brand-name defendants' motion, holding that the Weekses might be able to state a claim for relief under Alabama law if they could prove that the brand-name manufacturers had a duty to warn Mr. Weeks's physician about the risks associated with long-term use of brand-name Reglan® and, further, that the Weekses, as third parties, had a right to enforce an alleged breach of that duty.

Within the last year alone, federal district courts in this State have issued four decisions addressing the question whether brand-name Reglan® manufacturers can be held liable on fraud, misrepresentation, and/or suppression theories for physical injuries allegedly caused by plaintiffs' ingestion of generic metoclopramide. The first two courts answered no; however, this Court held otherwise, thereby creating an intrastate split. *Compare Simpson v. Wyeth, Inc.*, No. 7:10-CV-01771-HGD, 2010 WL 5485812 (N.D. Ala. Dec. 9, 2010), *report and recommendation adopted by*

2011 WL 10607 (N.D. Ala. Jan. 4, 2011) (holding that a brand-name manufacturer has no duty under Alabama law to warn of the risks associated with a competitor's generic product); *Mosley v. Wyeth, Inc.*, 719 F. Supp. 2d 1340 (S.D. Ala. 2010) (same), *with Weeks v. Wyeth, Inc.*, No. 1:10-cv-602, 2011 WL 1216501, at *3 (M.D. Ala. Mar. 31, 2011) (denying brand-name manufacturers' motion to dismiss on the ground that the plaintiffs there had pleaded a claim "that defendants perpetrated a fraud on the physician"); *see also Barnhill v. Teva Pharm. USA, Inc.*, No. Civ. 06-0282-CB-M, 2007 WL 5787186, at *1–*2 (S.D. Ala. Apr. 24, 2007) (holding that a brand-name manufacturer of the drug Keflex has no duty under Alabama law to warn of the risks associated with a competitor's generic product). Since this Court's decision, another district court in Alabama has followed the earlier decisions. *See Overton v. Wyeth, Inc.*, No. CA 10–0491–KD–C, 2011 WL 1343392 (S.D. Ala. Mar. 15, 2011), *report and recommendation adopted by* No. CA 10–0491–KD–C, 2011 WL 1343391 (S.D. Ala. Apr. 7, 2011).

Certification is appropriate here to resolve the disagreement among the federal district courts within Alabama and to prevent both federal courts within the State and state courts around the country from having to "mak[e] unnecessary *Erie* guesses" about unsettled questions of Alabama law. *Tobin v. Michigan Mut. Ins. Co.*, 398 F.3d 1267, 1274 (11th Cir. 2005); *see also, e.g.*, *Lehman Bros. v. Schein*, 416 U.S. 386, 391 (1974) (noting that certification often "save[s] time, energy, and resources and helps build a cooperative judicial federalism"). "Because the only authoritative voice on Alabama law is the Alabama Supreme Court, it is axiomatic that that court is the best one to decide issues of Alabama law." *Blue Cross & Blue Shield of Ala., Inc. v. Nielsen*, 116 F.3d 1406, 1413 (11th Cir. 1997).

The question framed below satisfies the requirements of Ala. R. App. P. 18(a): *first*, it presents a pure question of Alabama law; *second*, it is "determinative" of this case in the sense that

a negative answer would require dismissal of the Weekses' claims against the brand-name Defendants; and *third*, although two Alabama *trial* courts have addressed the question whether a brand-name manufacturer can ever be held liable for physical harm caused by a generic product and answered it in the negative,[1] the Alabama Supreme Court has never considered or resolved either that question or the subsidiary question whether a plaintiff claiming physical injury can prevail on fraud, misrepresentation, and/or suppression theories under these facts.

Considerations of judicial efficiency likewise counsel certification. During the last year, the number of Reglan®/metoclopramide cases nationwide ballooned from 250 to approximately 3500. Current estimates suggest that among the 3500 cases there are at least 250 Alabama-resident plaintiffs and that most (if not all) of these plaintiffs assert the fraud, misrepresentation, and/or suppression theories asserted here. The Alabama Supreme Court's definitive resolution of the question presented will therefore affect not only cases pending (or that might later arise) in this State, but also the scores of Alabama-resident cases pending in courts around the country—particularly in large consolidated actions pending in California, New Jersey, and Pennsylvania. Moreover, the question's significance extends well beyond the Reglan® litigation—and for that matter, even beyond pharmaceutical litigation. It is likely to recur any time a brand-name manufacturer (of any product) is sued on fraud, misrepresentation, and/or suppression theories by a plaintiff who claims to have been injured while using a generic-equivalent product.

(3) *Question to be Certified*

[1] *See Buchanan v. Wyeth Pharm., Inc.*, No. CV-2007-900065, Order at 1 (Ala. Cir. Ct. Oct. 20, 2008); *Green v. Wyeth Pharm., Inc.*, No. CV-06-3917 ER, 2007 WL 6428717, at *1 (Ala. Cir. Ct. May 14, 2007).

> **"Under Alabama law, may a drug company be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture or distribution of a brand-name drug, by a plaintiff claiming physical injury from a generic drug manufactured and distributed by a different company?"**

The phrasing used in this certified question should not restrict the Supreme Court's consideration of the problem posed by this case. This extends to the Supreme Court's restatement of the issue and the manner in which the answer is given. To assist the Supreme Court's consideration of the case, the entire record shall be transmitted to the Supreme Court of Alabama.

DONE this the 25th day of August, 2011.

/s/ Mark E. Fuller
UNITED STATES DISTRICT JUDGE