

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

JANE HALL	:	CIVIL ACTION
	:	
v.	:	
	:	
WYETH, INC, ET AL.	:	NO. 10-00738

MEMORANDUM

BUCKWALTER, S. J.

September 30, 2010

I. DISCUSSION

Plaintiff is a Michigan citizen who alleges that she was injured by the hormone therapy drug, Prempro. Her First Amended Complaint includes claims of negligence, fraud, strict liability, and breach of warranty. (First Am. Compl., attached as Ex. B to Defs.’ Mot. Dismiss.) Defendants are pharmaceutical manufacturers located in New York, New Jersey, and Pennsylvania. Currently before the Court is Defendants’ Motion to Dismiss this action in its entirety. Defendants’ argument for dismissal proceeds in two steps. First, they argue that Michigan law applies to this matter and that Michigan law immunizes drug manufacturers from liability in actions related to drugs approved by Food and Drug Administration. Next, they observe that Michigan law creates an exception to this immunity where the drug manufacturer defrauded the FDA, but they argue that the Food, Drug, and Cosmetic Act (“FDCA”) preempts any attempt to rely on the fraud exception in the absence of an FDA finding of fraud. We find that Michigan law does apply to Plaintiff’s claims, but we reject Defendants’ preemption argument. We therefore deny Defendants’ Motion to Dismiss.

A. Choice of Law

Michigan law applies to the resolution of this matter. Under Pennsylvania choice of law rules, a court must first determine whether a true conflict exists, and if there is a true conflict, the court must then determine which state has the greater interest in applying its law. Blain v. Smithkline Beecham Corp., 240 F.R.D. 179, 192-93 (E.D. Pa. 2007). Here, Michigan law by statute immunizes drug manufacturers from liability in product liability actions involving a product that was approved for safety and efficacy by the FDA unless the manufacturer “[i]ntentionally withholds from or misrepresents to the [FDA] information concerning the drug.” Mich. Comp. Laws § 600.2946(5)(a). Pennsylvania has no similar grant of immunity, and a true conflict therefore exists. Because Plaintiff is a Michigan citizen who was prescribed Prempro in Michigan, ingested the drug in Michigan, and suffered injury in Michigan, Michigan’s interest in applying its law is greater than Pennsylvania’s interest even though Defendants conduct operations in Pennsylvania. See Wolfe v. McNeil-PPC, Inc., No. 07-348, 2010 WL 3025805 (E.D. Pa. Jul. 30, 2010) (applying Maine law where plaintiff ingested drug in Maine and Defendants manufactured, tested, and marketed the drug in Pennsylvania); Bearden v. Wyeth, 482 F. Supp. 2d 614, 620-22 (E.D. Pa. 2006) (applying Arkansas law where Arkansas plaintiff ingested drug in Arkansas and defendant conducted research and development of the drug in Pennsylvania and made representations, warnings, and warranties in Pennsylvania). In sum, we find that there is an actual conflict between Pennsylvania law and Michigan law and that Michigan law has a greater interest in the application of its law. Accordingly, we apply Michigan law.

B. Application of Michigan Law

Michigan common law is not preempted by the FDCA. As set forth above, Michigan law grants immunity to drug manufacturers in actions involving drugs approved by the FDA unless the defendant engaged in fraud during the application process. Mich. Comp. Laws § 600.2946(5)(a). On its face, the statute would appear to allow a plaintiff to proceed by either alleging that the FDA has made a finding of fraud or by alleging facts that would support a finding of fraud by the state or federal court in which the plaintiff is proceeding. In the present matter, Plaintiff does not allege that the FDA has made any finding of fraud, and she instead proceeds by alleging facts that she believes support a finding of fraud.

As recognized by Defendants, a prior decision in this district held that to the extent the Michigan statute at issue permitted such claims, it was preempted by the FDCA. Henderson v. Merck & Co., No. 04-5987, 2005 WL 2600220, at *9-11 (E.D. Pa. Oct. 11, 2005). That decision relied on the Sixth Circuit's application of Buckman Co. v. Pls.' Legal Comm., 531 U.S. 341 (2001), which according to the Sixth Circuit "teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." Garcia v. Wyeth-Ayerst Laboratories, 385 F.3d 961, 966 (6th Cir. 2004). The Sixth Circuit therefore held that Michigan state tort law was preempted in such cases unless there had been an FDA finding of fraud. Id. Under this reading of federal preemption doctrine, Plaintiff's claims in this case would have to be dismissed because Plaintiff has not alleged an FDA finding of fraud. Subsequent to the Garcia decision, however, the Second Circuit issued an opinion in this area of law.

Specifically, in Desiano v. Warner-Lambert & Co., the Second Circuit was called upon to determine the preemptive effect of the FDCA on Michigan tort law in light of § 600.2946(5)(a). 467 F.3d 85 (2d Cir. 2007), aff'd Warner-Lambert Co., LLC v. Kent, 552 U.S. 440 (2008) (per curiam) (4-4 decision). The Second Circuit explicitly disagreed with the Sixth Circuit's application of Buckman. As observed by the Second Circuit, the Supreme Court recognizes a presumption against federal preemption of state law. Medtronic v. Lohr, 518 U.S. 470, 475 (1996). This presumption did not apply in the Buckman case because the California state law under which the plaintiff sought damages created a new cause of action for fraud on the FDA and therefore conflicted with the policing powers afforded to the FDA by the FDCA. Desiano, 467 F.3d at 93. The Michigan statute at issue in this case, on the other hand, "cannot reasonably be characterized as a state's attempt to police fraud against the FDA." Id. at 94. Rather, the object of the Michigan legislature was to "regulate and restrict when victims could continue to recover under preexisting state products liability law." Id. at 95. The Michigan legislature did not create a new cause of action based on a "newly concocted duty between a manufacturer and a federal agency." Id. at 94-95. Rather, Plaintiff's claims are based on pre-existing common law claims; proof of fraud on the FDA is not alone sufficient to impose liability under the Michigan statute. Id. at 94-95; see also Garcia, 385 F.3d at 965-66 (acknowledging that § 600.2946(5) "presents a somewhat different legal regime from the one invalidated in Buckman" because the "Michigan legislature has provided a general immunity for drug manufacturers with a specific exception for circumstances involving . . . fraud on the FDA rather than a specific cause of action for fraud on the FDA"). Proof of fraud is not even an element of their claims under Michigan law, and this issue only arises if the drug manufacturer chooses to assert § 600.2946(a), which the Michigan

Supreme Court has defined as a defense. Desiano, 467 F.3d at 96 (citing Taylor v. Smithkline Beecham Corp., 658 N.W.2d 127, 131 (Mich. 2003)). Unlike policing fraud on the FDA, it is within the prerogative of state legislatures to “regulat[e] matters of health and safety,” and the presumption against preemption therefore applies. Id. at 95. For these reasons, the Second Circuit found that the FDCA did not have preemptive effect on state common law claims under Michigan law. Id. The Sixth Circuit itself has since adopted the Second Circuit’s reading of Buckman. See Wimbush v. Wyeth, --- F.3d ----, 2010 WL 3256029, at *8-10 (6th Cir. Aug. 18, 2010) (holding that FDCA does not preempt Ohio negligence claims and stating that “the case law supports the conclusion that Congress did not intend to preempt state tort law claims when it passed the FDCA” (quoting Desiano, 467 F.3d at 94-95)). Like the Sixth Circuit in the Wimbush decision, we find the Second Circuit’s reasoning persuasive, and we accordingly reject Defendants’ preemption argument.

II. CONCLUSION

For the reasons set forth above, Defendants’ Motion to Dismiss is DENIED.

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ORDER

AND NOW, this 30th day of September 2010, upon consideration of Defendants' Motion to Dismiss (Doc. No. 7), Plaintiff's Response in Opposition thereto (Doc. No. 12), and Defendants' Reply in Further Support thereof (Doc. No. 15), it is hereby **ORDERED** that Defendants' Motion to Dismiss (Doc. No. 7) is **DENIED**.

BY THE COURT:

s/ Ronald L. Buckwalter
RONALD L. BUCKWALTER, S.J.