

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

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| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION |) | |
| _____ |) | MDL NO. 1203 |
| SHEILA BROWN, et al. |) | |
| v. |) | NO. 99-20593 |
| AMERICAN HOME PRODUCTS CORPORATION |) | |
| _____ |) | |
| THIS DOCUMENT RELATES TO: |) | |
| RAGENA J. MIZE CROWE, et al. |) | |
| v. |) | NO. 07-20002 |
| WYETH, et al. |) | |
| _____ |) | |

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

Bartle, C.J.

April 2, 2009

On October 23, 2006, Ragena J. Mize Crowe, individually, as authorized personal representative of the estate of her deceased husband, Russell E. Crowe, and as next friend for and on behalf of her children, Rachelle J. Crowe and Ryan R. Crowe, brought suit in the United States District Court for the Western District of Missouri for injuries Mr. Crowe sustained after taking Pondimin, a schedule IV prescription drug¹

1. A schedule IV prescription drug cannot be marketed without a prescription.

manufactured and distributed by the defendant, Wyeth,² and prescribed to his wife, Ragen Crowe. The complaint filed by Mrs. Crowe in October of 2006 contains causes of action grounded on negligence and negligence per se (Count I), design and marketing defect (Count II), failure to warn, inadequate and false warnings (Count III), misrepresentation and fraudulent misrepresentation (Count IV), strict products liability (Count V), and breach of implied warranty of merchantability (Count VI).

In January of 2007, the plaintiffs' case was transferred to this court for coordinated or consolidated pretrial proceedings as part of the Diet Drug Multi-District Litigation. Now pending before the court is the motion of Wyeth for summary judgment with respect to all six counts of the plaintiffs' complaint.

Pursuant to Rule 56(c) of the Federal Rules of Civil Procedure, summary judgment should be "rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A dispute is genuine if the evidence is such that a reasonable jury could return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A factual dispute is material when it "might affect the outcome of the suit under the governing law."

2. Wyeth was formerly known as American Home Products Corporation.

Id. After reviewing the evidence, the court makes all reasonable inferences from the evidence in the light most favorable to the non-movant. In re Flat Glass Antitrust Litig., 385 F.3d 350, 357 (3d Cir. 2004).

The following facts are either undisputed or viewed in the light most favorable to the plaintiffs.

In 1993 or 1994, Mrs. Crowe obtained a prescription for "fen-phen," but was unable to ingest the drug because it made her "dizzy and nauseous." Aff. of Ragen Mize Crowe, ¶ 3. Thereafter, Russell Crowe, the husband of Ragen Crowe, took her prescription drug because the Crowes did not have prescription drug coverage under their health insurance and had "virtually no spending money." Id. According to Mrs. Crowe, Russell Crowe took the pills for 2 to 3 months in 1993 or 1994 and for a month in 1997. Id. In January, 2000, the Mayo Clinic diagnosed Mr. Crowe with primary pulmonary hypertension ("PPH"), a progressive lung disorder in which the blood pressure in the pulmonary arteries rises above normal levels.³ Mr. Crowe underwent a heart and lung transplant surgery three years later in September of 2003. He died the following month.

3. Contrary to Mrs. Crowe's affidavit detailing her husband's ingestion of Pondimin, a Mayo Clinic Report, dated December 14, 2000, states that Mr. Crowe did not have exposure to appetite suppressants. See Ex. C to Wyeth's Mot. for Simm. J. This is confirmed in a Mayo Clinic report, dated December 13, 2002, which states that he has never been on medications to lose weight. See Ex. D to Wyeth's Mot. for Simm. J.

The parties appear to agree that the law of the transferor jurisdiction, Missouri, governs this dispute. Wyeth moves for summary judgment with respect to all counts of the plaintiffs' complaint. Wyeth claims that relief is barred under Missouri's learned intermediary doctrine. Krug v. Sterling Drug, Inc., 416 S.W.2d 143, 146 (Mo. 1967); Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419 (Mo. Ct. App. 1999); Johnston v. Upjohn Co., 442 S.W.2d 93, 95 (Mo. Ct. App. 1969); Kirsch v. Picker Int'l, Inc., 753 F.2d 670 (8th Cir. 1985). Under this doctrine, manufacturers of prescription drugs have "a duty to properly warn the doctor of the dangers involved." Kirsch, 753 F.2d at 671 (quoting Krug, 416 S.W.2d at 146). This warning provided to the physician "is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of prescription drugs." Id. (citing Johnston, 442 S.W.2d 93 at 95).

A plaintiff seeking to overcome the learned intermediary doctrine must prove that: (1) the warnings given by the drug manufacturer to the healthcare provider were inadequate; and (2) the inadequate warnings were the proximate cause of plaintiff's injuries. Madsen v. Am. Home Prods. Corp., 477 F. Supp. 2d 1025, 1035 (E.D. Mo. 2007) (citing In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 821 (E.D. Tex. 2002)). Thus, "'even assuming the warnings are inadequate, plaintiffs must show that a proper warning would have changed the decision of the treating physician, i.e. that but for the inadequate warning, the treating physician would not have used or

prescribed the product.'" See id. (quoting In re Norplant, 215 F. Supp. 2d at 821).

According to Wyeth, Mr. Crowe did not have a prescribing physician and, therefore, plaintiffs cannot present testimony that an adequate warning would have changed the prescribing physician's decision to prescribe Pondimin. Plaintiffs counter that the learned intermediary doctrine is inapplicable for several reasons. They assert that: (1) Wyeth's conduct was intentional and calculated; (2) Wyeth engaged in or allowed direct marketing to consumers; (3) Wyeth engaged in a scheme designed to take doctors out of their role of learned intermediary; and (4) Wyeth took an official position that a learned intermediary was unnecessary. Plaintiffs' opposition, however, is completely devoid of any citation to legal authority supporting any of these propositions. Based on Missouri precedent, the learned intermediary doctrine applies to bar the plaintiffs' cause of action for failure to warn alleged in Count III of the complaint. Kirsch, 753 F.2d 670; see also Perotti v. Johnson & Johnson Vision Prods., No. 84278, 2004 WL 3016092, *1 (Ohio Ct. App. Dec. 30, 2004).

Wyeth argues that the learned intermediary doctrine also applies to all of the remaining claims for negligence and negligence per se (Count I), design and marketing defect (Count II), misrepresentation and fraudulent misrepresentation (Count IV), strict products liability (Count V), and breach of implied

warranty of merchantability (Count VI) because these are premised on a failure to warn on the part of Wyeth. We disagree.⁴

The learned intermediary doctrine only applies to claims based on a failure to warn theory. Kirsch, 753 F.2d at 671. A review of plaintiffs' complaint reveals an intention to pursue claims in addition to Wyeth's alleged failure to warn. For example, in the first count of the complaint, which is grounded on negligence and negligence per se, plaintiffs allege that Wyeth failed to exercise ordinary care in the design, marketing, manufacture, sale, testing, quality assurance, quality control, and/or distribution of Diet Drugs. See Compl. at ¶¶ 50-51. In Count II of the complaint for design and marketing defect, plaintiffs allege that the Diet Drugs manufactured and/or supplied by Wyeth were defective in design or formulation. See id. at ¶¶ 59-60. Count IV of the complaint asserts a cause of action for misrepresentation and fraudulent misrepresentation and alleges that Wyeth made certain misrepresentations through its advertising, labeling, and other communications. See id. at ¶¶ 72, 74, 76. With respect to the strict products liability claim in Count V, plaintiffs allege that Wyeth formulated, designed, manufactured, distributed, marketed, and/or sold Diet Drugs that were defective and unsafe for their intended purpose.

4. Even Wyeth recognizes that not all of plaintiffs' claims rely solely on a failure to warn theory. Indeed, Wyeth states: "[t]he majority of Mr. Crowe's allegations are premised on failure to warn." (emphasis added). See Wyeth's Mot. for Summ. J. and Stay of Disc. at p. 4.

See id. at ¶¶ 80-81. Finally, plaintiffs allege in Count VI for breach of the implied warranty of merchantability that Wyeth breached the warranty that the Diet Drugs were of merchantable quality, safe and fit for their intended purpose. See id. at ¶ 88. These are independent causes of action and do not appear to be premised on Wyeth's alleged failure to warn. We hold that the learned intermediary doctrine only bars those claims whose gravamen is failure to warn.⁵ Specifically, Count III is dismissed in its entirety and Counts I, II, IV, V and VI are dismissed only to the extent they are based on failure to warn.

Wyeth next argues that plaintiffs' complaint is barred by the doctrine of in pari delicto because Mr. Crowe illegally ingested his wife's Pondimin. Plaintiffs respond that the doctrine of in pari delicto is not applicable to the facts of this case given the lesser culpability on the part of Mr. Crowe.

The doctrine of in pari delicto prohibits a plaintiff from maintaining an action when, "in order to establish his cause of action, he must rely, in whole or in part, on an illegal or immoral act or transaction to which he is a party," Dobbs v. Dobbs Tire & Auto Ctrs., Inc., 969 S.W.2d 894, 897 (Mo. Ct. App. 1998) (citing 1A C.J.S. Actions § 29 (1985)). Missouri courts have weighed the relative culpability of the parties when

5. Wyeth's reliance on Madsen is misplaced. First, the district court in Madsen was applying and construing Iowa law. 477 F. Supp. 2d at 1033. Second, the court specifically declined the defendant's "invitation to construe all of Plaintiff's claims as failure-to-warn claims." Id.

applying its equitable counterpart, the doctrine of unclean hands. Smith v. Holdoway Constr. Co., 129 S.W.2d 894, 902 (Mo. 1939); Pony Express Cmty. Bank v. Campbell, 206 S.W.3d 399, 402 (Mo. Ct. App. 2006).

Wyeth argues that it is inappropriate to balance the relative culpability of the parties in legal actions where damages are sought. In support of this argument, Wyeth cites three cases, Cork v. St. Charles County, 10 S.W.3d 608 (Mo. Ct. App. 2000), Dobbs, 969 S.W.2d 894 (Mo. Ct. App. 1998) and Clouse v. Myers, 753 S.W.2d 316 (Mo. Ct. App. 1988), which it argues illustrate that Missouri courts apply the doctrine of in pari delicto without "balancing the parties' culpability." However, none of these cases states that it is inappropriate to balance the relative culpability of the parties. Furthermore, the Missouri court of appeals has specifically stated that the "doctrine of *in pari delicto* is the legal counterpart to the equitable doctrine of unclean hands" and, as noted above, the relative culpability of the parties is weighed when applying that doctrine. Dobbs, 969 S.W.2d at 897; Smith, 129 S.W.2d at 902. In the cases cited by Wyeth, the courts simply found the parties to be in pari delicto or in equal fault and thus ruled for the defendant.

We acknowledge that in two of the cases cited by Wyeth the court concluded, on summary judgment, that the doctrine of in pari delicto barred plaintiff's recovery. Cork, 10 S.W.3d 608, Dobbs, 969 S.W.2d 894 (Mo. Ct. App. 1998). In each case,

however, there was no reasonable dispute that the conduct of plaintiff was equally culpable with that of the defendant.⁶

Here, we cannot say that, as a matter of law, plaintiffs are barred from relief. This is a question for the jury to decide. The Latin phrase "in pari delicto" literally means "in equal fault." We simply cannot conclude at this stage of the case that Mr. Crowe, who took his wife's prescription drugs, was in pari delicto or in equal fault with Wyeth.⁷

For the foregoing reasons, Wyeth's motion for summary judgment based on the in pari delicto doctrine will be denied.

6. In the third case, the court concluded the doctrine applied and plaintiff was denied relief after a non-jury trial. Clouse, 753 S.W.2d 316.

7. Wyeth also argues that the doctrine of in pari delicto bars plaintiffs' complaint because other courts, outside of Missouri, confronting claims based on illegal drug use have so found. Price v. Purdue Pharm. Co., 920 So.2d 479 (Miss. 2006), Foister v. Purdue, L.P., 295 F. Supp. 2d 693, 705 (E.D. Ky. 2003), and Pappas v. Clark, 494 N.W.2d 245, 246-48 (Iowa Ct. App. 1992). We are bound by the law of Missouri and, therefore, these cases are not controlling.

Russell E. Crowe, and as next friend for and on behalf of her children, Rachelle J. Crowe and Ryan R. Crowe, with respect to Count III of the complaint and with respect to Counts I, II, IV, V and VI but only to the extent these claims are based on a failure to warn; and

(4) the motion of Wyeth for summary judgment is DENIED in all other respects.

BY THE COURT:

/s/ Harvey Bartle III
C.J.