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

IN RE: DIET DRUGS (Phentermine/ Fenfluramine/Dexfenfluramine) PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 1203
THIS DOCUMENT RELATES TO:	:	
JUDITH MINGUS v. WYETH, et al.	:	CIVIL ACTION NO. 04-23744

MEMORANDUM

Bartle, C.J. April 21, 2006

Plaintiff Judith Mingus filed this action against Wyeth on July 9, 2004. She alleges that she is suffering from primary pulmonary hypertension ("PPH"), an almost always fatal condition, as a result of ingesting Wyeth's prescription diet drug Redux, which was withdrawn from the market in September, 1997. This court approved a Nationwide Class Action Settlement involving Wyeth's diet drugs Pondimin and Redux on August 28, 2000. See Pretrial Order ("PTO") No. 1415. While plaintiff is a class member, the Settlement Agreement exempts from the definition of "settled claims" those claims based on PPH and allows a class member with this condition to sue Wyeth in the tort system, as plaintiff has done here. See Settlement Agreement § I.53. In her complaint, plaintiff asserts claims for both negligence and strict product liability. It is undisputed that Ohio substantive law is applicable.

Plaintiff and defendant both have filed multiple motions for summary judgment. See Fed. R. Civ. P. 56. One of plaintiff's motions seeks summary judgment on "Wyeth's Learned Intermediary Defense" and one motion of Wyeth requests summary judgment "Based on Lack of Proof of Causation for Alleged Failure to Warn." On March 29, 2006, after the court held argument on these and other summary judgment motions, plaintiff filed a notice of withdrawal of her claim based on a failure to warn theory. In her notice to the court, plaintiff asserts that she still intends to pursue claims for negligence and strict product liability based on design defect. With respect to the design defect claim, she states that "Redux was so dangerous and defective in design that it should never have been on the market and no warning could be adequate."

There is no dispute that plaintiff's withdrawal of her failure to warn claim made moot plaintiff's motion for summary judgment on "Wyeth's Learned Intermediary Defense." In that motion, plaintiff sought a ruling from the court that the warnings that accompanied Redux were inadequate as a matter of law. The inadequacy of the warnings is an element of a failure to warn claim on which plaintiff has the burden of proof. See, e.g., Crislip v. TCH Liquidating Co., 556 N.E.2d 1177, 1182-83 (Ohio 1990).

Plaintiff further contends her notice of withdrawal serves to moot the motion of Wyeth for summary judgment "Based on Lack of Proof of Causation for Alleged Failure to Warn." In

response to plaintiff's notice, Wyeth now contends that the withdrawal of plaintiff's failure to warn claim also vitiates her claim that Redux was defectively designed. Specifically, Wyeth asserts that Ohio law requires a plaintiff asserting a strict liability claim for design defect in a prescription drug case to prove that the medication's warnings were inadequate. If Wyeth is correct, then plaintiff's withdrawal of her claim for failure to warn would undermine her strict liability claim for design defect. In addition, Wyeth contends plaintiff's negligence claim must fail in that her notice attempts to assert a negligence theory either not contained in her complaint or otherwise barred by state statute and preempted by federal law.

In Ohio, claims for strict liability based on design defect are governed by Ohio Revised Code § 2307.75. That section states that a product is defectively designed "if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design ... exceeded the benefits associated with that design." Ohio Rev. Code § 2307.75(A). This has been referred to as the "risk/utility test." See, e.g., In re Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 815 (N.D. Ohio 2004). In the alternative, a plaintiff may show a product is designed defectively under the "consumer expectations test," which requires proof that a product is more dangerous than an ordinary consumer would expect when the product is used in a reasonably foreseeable manner. Id.; see also Ohio Rev. Code § 2307.75(B)(5).

Regardless of whether a plaintiff seeks to prove a product is defective under either the risk/utility test or the consumer expectations test, § 2307.75(D) includes an additional provision applicable to prescription drugs such as Redux: "An ethical drug ... is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug or ethical medical device provides adequate warning and instruction under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect." Ohio Rev. Code § 2307.75(D). Wyeth contends that subsection (D) requires that plaintiff's design defect claim must be supported by a claim that the Redux warnings were inadequate. Plaintiff responds that subsection (D) is an affirmative defense which places the burden on defendants to show that the warnings were adequate. We agree with plaintiff.

The wording of § 2307.75(D) in our view makes the provision an affirmative defense. It does not require plaintiff to prove that the warning is inadequate. Rather, it provides a safe harbor for drug manufacturers if their warning is adequate. Unless the manufacturer proves that the warning is adequate, the safe harbor will not apply. In In re Meridia Products Liability Litigation, the District Court for the Northern District of Ohio read § 2307.75(D) in the same way we do. 328 F. Supp. 2d 791 (N.D. Ohio 2004). The court stated, "Generally, an adequate warning is a defense to design defect claims levied against prescription drugs." Id. at 815 (emphasis added). Another case

relied on by Wyeth, Kennedy v. Merck & Co., does not undermine this conclusion. See No. 19591, 2003 WL 21658613 (Ohio Ct. App. July 3, 2003). There, an Ohio intermediate court of appeals affirmed the entry of judgment on plaintiff's design defect claim only where it was "undisputed" that the drug's warning was adequate. Id. at *4. The burden of proof issue was not discussed.

Here, plaintiff has withdrawn her claim alleging a failure to warn--a claim on which she had the burden of proof that the Redux warnings were inadequate. This withdrawal, however, does not otherwise relieve defendant of its burden of proving that the warnings were adequate where plaintiff has a strict liability claim for design defect. Unlike the situation in Kennedy, plaintiff does not concede that the warning was adequate with respect to her design defect claim. Wyeth must carry the burden to show that the warnings were adequate under § 2307.75(D). The issue remains a question of fact for the jury at trial, and summary judgment for Wyeth must be denied on plaintiff's strict liability claim alleging a design defect.

In her withdrawal notice, plaintiff further states her intention to go to trial on her claim for "negligence in failing to investigate adverse reaction reports, and in other conduct below the industry standard of care as set forth in plaintiff's expert reports, leading to the failure to withdraw Redux from the market no later than March 1997." Wyeth contends that such a

theory was not asserted in the complaint and is otherwise barred by state statute and preempted by federal law.

First, we find that the complaint adequately asserted the negligence theory explained in plaintiff's notice of withdrawal. Paragraph 20 of the complaint clearly alleged that plaintiff would seek recovery based on defendant's "failing to adequately monitor the effects of the drugs, failing to make timely and adequate warning to the medical profession, failing to timely and accurately report to the FDA all adverse drug experience information obtained, and misrepresenting the results of studies to physicians and the public." We disagree with Wyeth's contention that plaintiff is attempting to assert a claim not now in her complaint. See, e.g., Fed. R. Civ. P. 8(a); Swierkiewicz v. Sorema N.A., 534 U.S. 506, 512-13 (2002).

Next, Wyeth contends that plaintiff's negligence claim is simply a "dressed up" design defect claim and is thus superseded by the Ohio Product Liability Act. There is no question that common law negligence claims survived enactment of the Act. See Carrel v. Allied Products Corp., 677 N.E.2d 795, 800 (Ohio 1997). We reject Wyeth's contention that plaintiff's negligence claim is duplicative of her design defect claim. Courts in Ohio have long recognized that a plaintiff may assert both negligence and strict product liability causes of action in the same case. See, e.g., Cincinnati v. Berretta USA Corp., 768 N.E.2d 1136, 1142-46 (Ohio 2002); Onderko v. Richmond Mfg. Co., 511 N.E.2d 388, 392 (Ohio 1987). While we make no judgment on

the merits of plaintiff's separate theories of recovery, there is no question she is permitted to pursue them both in same action.

Finally, Wyeth argues that plaintiff's claim is preempted by the Federal Food, Drug and Cosmetic Act. See 21 U.S.C. § 301 et seq. That Act exclusively vests the Food and Drug Administration ("FDA") with the duty and authority to evaluate the risks and benefits of drugs to be marketed in the United States. See 21 U.S.C. § 393(b); see also Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 343 (2001). Plaintiff, however, does not allege that Wyeth committed a fraud on the FDA in procuring FDA approval of Redux prior to its entrance on the market in 1996. Nor does plaintiff contend that the FDA never should have allowed Redux to be marketed in 1996. The allegations here are that Wyeth designed a defective product and was negligent in not taking Redux off the market sooner that it did. In essence, plaintiff contends that Wyeth failed in its post-approval duties. This theory is not preempted by federal law.

Accordingly, the motion of Wyeth for summary judgment "based on lack of proof of causation for alleged failure to warn" as well as the additional arguments raised in Wyeth's response to plaintiff's withdrawal of her claim of failure to warn must be denied in their entirety.

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ORDER

AND NOW, this 21st day of April, 2006, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the motion of plaintiff Judith Mingus for summary judgment on Wyeth's Learned Intermediary Defense is DENIED as moot; and

(2) the motion of defendant Wyeth for summary judgment based on lack of proof of causation for alleged failure to warn is DENIED.

BY THE COURT:

/s/ Harvey Bartle III
C.J.